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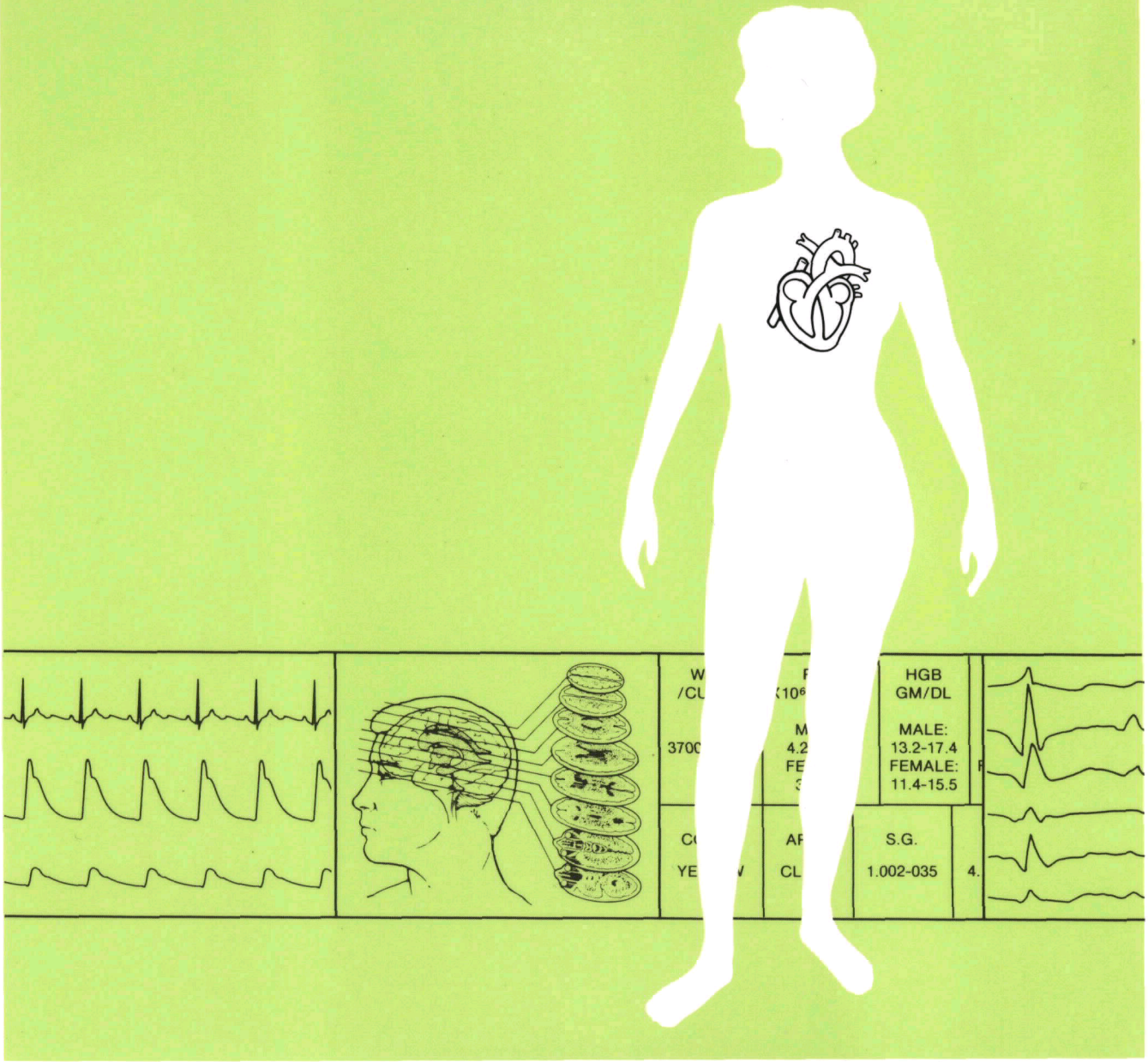
MEDICAL TECHNOLOGY MANAGEMENT



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MEDICAL TECHNOLOGY MANAGEMENT

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INTRODUCTION

Our society is constantly looking for ways to improve access to a higher quality, more efficient healthcare delivery system. Many strategies have been tried and others will be tested in the future, but it is clearly evident that we have not yet found the optimal approach. The healthcare delivery system in the U.S. continues to undergo a transformation as society strives to improve the access, quality, and cost-efficiency of the present system. Medical technology has been recognized as an important element of this transformation, and will continue to play a vital role.

Healthcare technology management professionals practicing in this industry need to understand the forces that shape this change so they can make their own contribution to improve the system. Because technology and medical equipment play a significant role in this process, there is a need to understand medical technology management and effectively communicate its function to healthcare leaders. To make technology's role more clinically effective and cost-effective, appropriate management tools are needed. The involvement of the clinical engineer or technology manager in the healthcare institution in making the best use of these tools is critical to a hospital's success. For example, this book will focus on strategic technology planning principles and how these principles can contribute to improved patient outcomes. Examples of their application and that of other tools will be given.

Section 1 defines basic terms and discusses the dynamics of the healthcare delivery system. In Section 2, the first tool – strategic technology planning – is described. Sections 3, 4, and 5 offer a practical approach to the development and implementation of an ongoing technology planning and technology management program that includes technology assessment, equipment assets management, and equipment acquisition and deployment. Tools for exploring the impact of medical technology on quality of patient care and risk management are described in Section 6.

Note: The authors wish to thank ECRI for making available material that is used in this book.

1.0 MEDICAL TECHNOLOGY MANAGEMENT—AN OVERVIEW

In the complex environment of the healthcare delivery system, we are beginning to understand the relationship between the methods and information that guide medical technology management decisions. While the magnitude of this relationship varies from one hospital to another, and from one patient population to another, every professional manager needs to synthesize and communicate technology-related information to multidisciplined workers as it directly impacts their patient-care services.

The healthcare delivery system is a complex environment wherein facilities, equipment, drugs, information, finance, and a full range of human interventions interact. It is in this clinical environment that patients, skilled staff, contract labor, and a wide variety of technologies converge. Definitions of terms used in this book are given below, along with a discussion of the dynamics of the healthcare delivery system.

1.1 *Definition of Terms*

(Note: Many of the definitions and ideas presented in this book are sourced with permission from ECRI and discussions with ECRI staff.)

1.1.1 Healthcare Technology

Healthcare technology includes the devices, equipment, systems, software, supplies, pharmaceuticals, biotechnologies, and medical and surgical procedures used in the prevention, diagnosis, and treatment of disease in humans; for their rehabilitation; and for assistive purposes. In short, technology is broadly defined as encompassing virtually all the human interventions intended to cope with disease and disabilities, short of spiritual alternatives. This book focuses on medical equipment products (devices, systems, and software), rather than pharmaceuticals, biotechnologies, or procedures.[1] The concept of technology also encompasses the facilities that house both patients and products. Facilities cover a wide spectrum—from the modern hospital on one end to the mobile imaging trailer on the other.

1.1.2 Clinical Engineers/Biomedical Engineers

As the authors began describing the issues with the management of medical technology, it became obvious that some of the terms are being used interchangeably in the literature. For example, the terms engineers, clinical engineers, biomedical equipment technicians, equipment managers, and healthcare engineers are frequently used. For clarification, in this book the authors will refer to clinical engineers and the clinical engineering department as a representative group for all of these terms.

1.1.3 Technology Assessment

Assessment of a medical technology is any process used for examining and reporting properties of medical technology used in healthcare, such as safety, efficacy, feasibility, and indications for use, cost, and cost-effectiveness, as well as social, economic, and ethical consequences, whether intended or unintended.[2]

A *primary* technology assessment is one that seeks new, previously nonexistent data through research, typically employing long-term clinical studies of the type described below. A *secondary* technology assessment is usually based on published data, interviews, questionnaires, and other information-gathering methods, rather than original research that creates new, basic data.

The following are six technology assessment objectives:[3]

- Ongoing monitoring of developments concerning new and emerging technologies.
- Assessment of the clinical efficacy, safety, and cost benefit ratio of specific new technologies, including their effects on established technologies.
- Evaluation of short and long-term costs and benefits of alternate approaches to managing specific clinical conditions.
- Evaluation of the appropriateness of existing technologies and their clinical uses, along with the identification of outmoded technologies and their elimination from duplicative uses.
- Evaluation of specific technology-based interventions in terms of improved overall value (quality and outcomes) to patients, providers, and payers.
- Facilitate continuous match between needs, offerings, and capabilities.

The locally based (hospital or hospital group) technology assessment described in this book is a process of secondary assessment that attempts to judge whether a certain medical equipment/product can be assimilated into the local operational environment.

1.1.4 Appropriate Technology

Appropriate technology is a term initially used in developing countries, referring to selecting medical equipment that can "appropriately" satisfy the following constraints: funding shortages, insufficient numbers of trained personnel, lack of technical support, inadequate supplies of consumables/accessories, unreliable water and power utilities/supplies, and lack of operating and maintenance manuals.

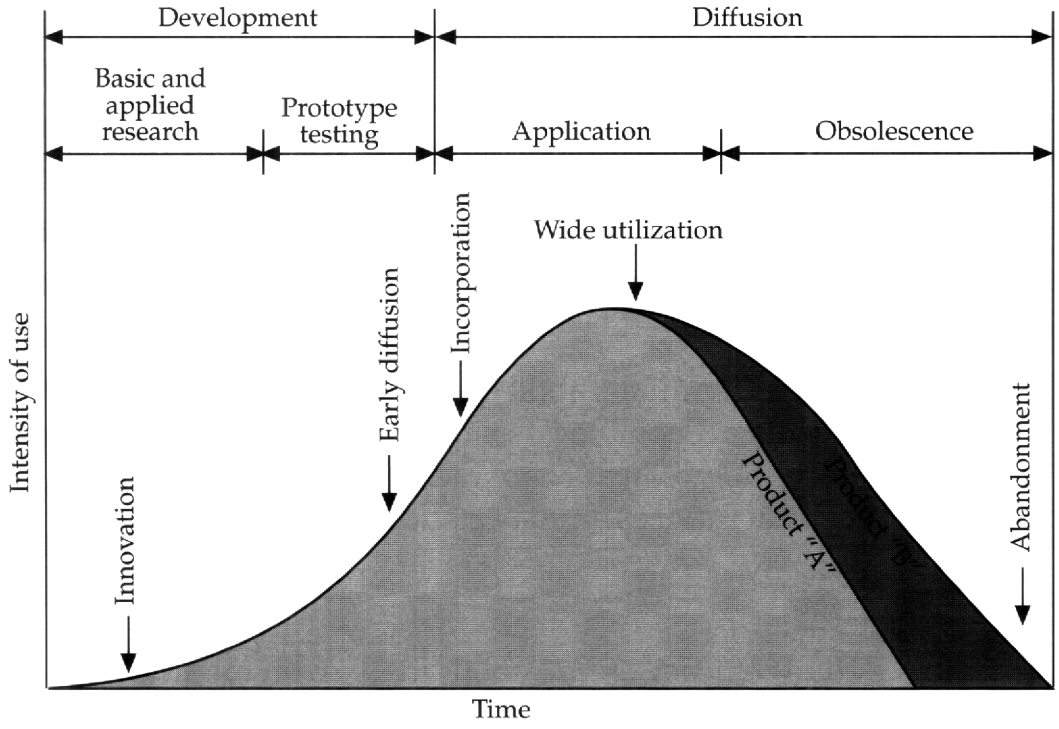
In the context of this book, appropriate technology selection must take into consideration local health needs and disease prevalence, the need for local capability of equipment maintenance, and availability of resources for ongoing operational and technical support.

1.1.5 Technology Diffusion

Technology diffusion is the process by which a technology is spread over time in a social system. Stages of technology diffusion are as follows:

- "Emerging: in the applied research stage, about the time of initial clinical testing.
- New: past the stage of clinical trials but not yet in widespread use.
- Established: considered by providers to be a standard approach to a particular condition and diffused into general use.
- Obsolete/outmoded: superseded by another technology and/or demonstrated to be ineffective or harmful."[4]

Figure 1.1 – Technology life-cycle.



1.1.6 Technology Life-Cycle

Technology has a life-cycle — a process by which it is created, tested, applied, and replaced or abandoned. Since the life-cycle goes from basic research and innovation to obsolescence and abatement, as shown in Figure 1.1, it is critical to know the maturity of a technology prior to making decisions regarding its adoption. Technology forecast and assessment of pending technological changes are the investigative tools that support systematic and rational decisions about the utilization of a given institution's technological capabilities.

1.1.7 Cost–Effectiveness

Cost-effectiveness combines quantitative and qualitative considerations. Product life-cycle cost analysis (which, in turn, includes initial purchase price, shipping, renovations, installation, supplies, associated disposables, cost per use, and similar quantitative measures) is a critical analysis measurement. Life-cycle cost also takes into account staff training, ease of use, service, and many other cost factors. But experience and judgment about the relative importance of features and the ability to ful-

fill the intended purpose also contribute critical information to the cost-effectiveness equation.[1]

"Cost-effectiveness can be defined as the costs of a project (product or system) or of alternative projects compared to the resultant benefits, with cost and benefits/effectiveness not expressed by the same unit. Costs are usually expressed in dollars, but benefits/effectiveness are ordinarily expressed in terms such as lives saved, disability avoided, quality-adjusted life years saved, or other relevant objectives."[2]

1.1.8 Access

Access is an individual's ability to obtain medical services on a timely and financially acceptable basis. Ease of access is determined by such factors as location of healthcare facilities, availability of and completeness of medical services, transportation, and hours of operation.[4]

1.1.9 Efficacy

Banta defines efficacy as "a benefit for a given medical problem under ideal conditions of use."[2]

1.1.10 Effectiveness

Banta defines effectiveness as "a benefit for a given medical problem under average conditions of use."[2]

1.1.11 Ease of Use

Ease of use should be verified as part of the clinical evaluation of equipment prior to purchase decision. It includes the concept of inservice training and documentation that readily prepares equipment users and maintenance personnel for appropriate equipment operation; the concept of user's ability; and the concept that proper human factors have been taken into account in equipment design—such as placing and spacing of necessary device controls so that equipment users can operate equipment with minimum patient and user discomfort.[5]

1.1.12 Strategic Technology Planning

Strategic technology planning encompasses both technologies new to the hospital and replacements for existing equipment that are to be ac-

quired over several quarters. Acquisitions can be proposed for reasons related to safety, standard-of-care issues, and age or obsolescence of existing equipment. Acquisitions can also be proposed to consolidate several service areas, to expand a service area, to reduce cost of service or to add a new service area.

Strategic technology planning optimizes the way the hospital's capital resources contribute to its mission. It encourages selecting new technologies that are cost-effective, and it also allows the hospital to be competitive by offering state-of-the-art services. Strategic technology planning works for a single department, product line, or clinical service. It can be limited to one or several high-priority areas. It can also be used for an entire multihospital system or geographical region.[6]

1.1.13 Technology Planning and Management

Technology planning and management is an accountable, systematic approach to ensuring that cost-effective, efficacious, appropriate, and safe equipment is available to meet the demands of quality patient care, and allows an institution to remain competitive. Elements include: in-house service management, management and analysis of external service providers, involvement in the equipment acquisition process, involvement of appropriate hospital personnel in facility planning and design, involvement in reducing technology-related patient and staff incidents, training equipment users, reviewing equipment replacement needs, and ongoing assessment of emerging technologies.[6]

1.1.14 Equipment Assets Management

Equipment assets management encompasses the traditional duties of the hospital clinical engineering department. This includes involvement in equipment acquisition and other life-cycle issues, technical support for equipment, supplying equipment information and training, monitoring and evaluating equipment, and documenting equipment. It also includes using equipment management information to provide a more complete analysis of specific financial and clinical indicators, as well as for compliance with regulatory and accreditation requirements.

1.1.15 Equipment Acquisition and Deployment

Medical device systems and products typically emerge from the strategic technology planning process as "required and budgeted" needs. The

process that follows, which ends with equipment acceptance testing and placement into general use, is known as the equipment acquisition and deployment process.

1.1.16 Quality of Care

Quality of care refers to an organization's objectives of providing care with the most efficient use of resources. Objectives of care may include the following: patient satisfaction; promotion, safeguarding, and restoration of health; appropriate interactions between patients and healthcare practitioners; proper service setting for healthcare delivery; ease of access; empathy of physicians; proper technical quality; and the clinical competence of healthcare practitioners.[4]

1.1.17 Quality Assurance or Quality Improvement

Quality Assurance (QA) and Quality Improvement (QI) are formal sets of activities to measure the quality of care provided; these usually include a process for selecting, monitoring, and applying corrective measures.[2] The 1992 Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) standards require hospital QA programs to focus on patient outcomes as a primary reference. JCAHO standards for Plant, Technology and Safety Management (PTSM), in turn, require certain equipment management practices and QA or QI activities. Identified QI deficiencies may influence equipment planning, and QI audits may increase awareness of technology overuse or underutilization.

1.1.18 Risk Management

Risk management is a program that helps the hospital avoid exposure to risks, minimize liability exposure, and stay compliant with regulatory reporting requirements. JCAHO PTSM standards require minimum technology-based risk management activities. These include clinical engineering's determination of technology-related incidents with follow-up steps to prevent recurrences, and evaluation and documentation of the effectiveness of these steps.

1.1.19 Standards

A wide variety of formal standards and guidelines related to healthcare technology now exists. Some standards apply to design, development,

and manufacturing practices for devices, software, and pharmaceuticals; some are related to the construction and operation of a healthcare facility; some are safety and performance requirements for certain classes of technologies, such as standards related to radiation or electrical safety; and others relate to performance, or even construction specifications, for specific types of technologies.

Other standards and guidelines deal with administrative, medical, and surgical procedures and the training of clinical personnel. Standards and guidelines are produced and/or adopted by government agencies, international organizations, and professional and specialty organizations and societies. ECRI's Healthcare Standards Directory lists over 13,000 individual standards and guidelines produced by over 800 organizations and agencies from North America alone![7]

1.1.20 Safety

Safety is the condition of being safe from danger, injury, or damage. It is judgment about the acceptability of risk in a specified situation (e.g., for a given medical problem) by a provider with specified training, at a specified type of facility equipment.[3]

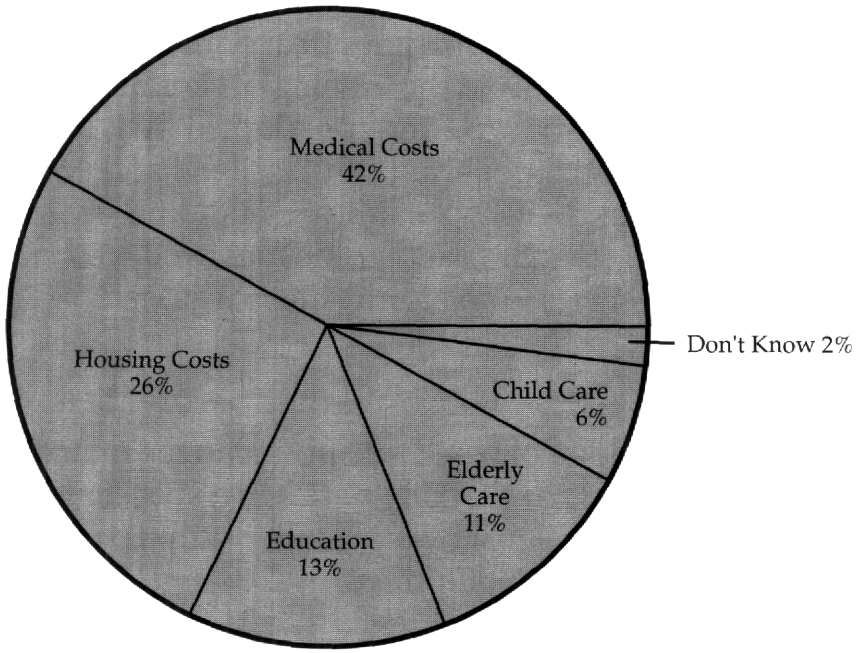
1.2 *The Healthcare Delivery System*

The healthcare delivery system, which includes private-sector and government systems, is undergoing a transition driven by many forces. This section will focus on three of those forces: cost, technology, and the expectations of society. The relative impact of these forces may change in significance. In addition, the human factors that interact with these forces are changing, creating a crisis that is the subject of public debate. It is clear, however, that the system is under mounting pressure to (1) identify its goals, (2) select and define priorities, and (3) wisely allocate limited resources.

Healthcare providers are faced with a vortex of cost and technology factors, and with society's expectations for the implementation of improved quality of care and the containment of medical expenditures. To date, there is little data or agreement on the methods available to measure the needed quality improvements, especially those related to the cost of technology, often leaving hospitals without clear direction for meeting these expectations. As to cost containment, public fears were re-

flected in a survey in which people were asked to express the greatest financial burden they expected to bear in the 1990s. Medical cost was selected by 42% of those surveyed, as shown in Figure 1.2.[8]

Figure 1.2 – Public perception of greatest financial burdens in the 1990s.



Source: Modern Healthcare Weekly Business News, 1991.

The data in Figure 1.2 exists despite legislation already passed in the 1980s limiting reimbursement for services provided by hospitals, currently proposed legislation which plans to further limit reimbursement for certain services, and plans concerning limitations on capital spending that will discourage a number of hospitals from acquiring new technology on credit. Most hospitals feel that they have addressed the majority of the administrative-related issues directly relating to cost efficiency and now need to focus on technology-related costs.

One apparent solution for hospitals (to bring a sense of order and stability to this volatile environment) is to seek ways to become more effective managers of, among other things, their available technology resources, and, in the future, to do more with less available capital by selecting only appropriate technologies. Many hospitals are beginning to recognize this and can be expected to focus significant energy in the 1990s on achieving the proper balance of cost-effectiveness, quality of care, and access with respect to their technology assets. Technology

management programs will steer hospitals through these transitional times by improving their performance and reducing their costs.

1.2.1 Private Sector Healthcare Delivery System

The private sector primarily includes single hospitals and multihospital systems that are privately owned. Their primary mission is to deliver quality patient care services that meet the needs and maintain the health of the communities they serve, with secondary goals of teaching, clinical research, and profit. Table 1.1 further defines the multihospital system.

The key hospital participants with respect to technology strategic planning are:

- Administrative/management team, primarily including administrator (CEO), associate administrator (COO), and controller (CFO).
- Physicians.
- Director of Nursing and other department heads.
- Director of Biomedical/Clinical Engineering.
- Other direct care providers.

Table 1.1 - Multihospital Private System

Participants	Administration/management team
	CEO, CFO, etc.
	Physicians, Director of Nursing and other department heads
	Direct care providers
	Regional and national leadership
	Regional and national staff experts in various healthcare and technology issues
Payer	Patients, employers, government reimbursement, insurance companies
Payees	Physicians, hospitals
Mission	Healthcare delivery (medical), HMOs also provide preventive medicine services.

Of the participants, the administrative team and Director of Nursing are often corporate employees, while the rest are local hospital employees. The local management team is guided by regional and national leadership.

The healthcare system participants are greatly affected by the key payers: patients, employers, federal government (Medicare), and private insurance companies. Typical private hospitals may have up to 50% of patients supported by Medicare, so reimbursement by the federal government is a major factor in their annual revenues. Employer payments for healthcare insurance have risen sharply in recent years for the typical private patient. For most of the 1980s, patients did not have to directly pay their own healthcare costs and had little personal incentive to contain them. However, the continued rising costs of healthcare have forced payers to place a greater financial responsibility on patients, causing many employers and private hospital patients to turn to managed care (prepaid) healthcare providers.

Delivery system payees (predominantly hospitals) have seen their reimbursement per patient day and their inpatient profit margins decrease. This has placed greater pressure on payees to deliver more care in alternative settings, such as less expensive outpatient clinics, and to make the correct choices for technology to help them meet their goals. Some typical private hospital goals are:

- Provide quality services that maintain the health of the community.
- Increase insured patient referrals.
- Attract the highest quality physicians.
- Receive acknowledgment for quality patient care.
- Retain compliance with accreditation and state agencies.
- Remain competitive.
- Sustain positive fiscal performance.

1.2.2 Government Sector Healthcare Delivery System

The government healthcare delivery system includes the Department of Veterans Affairs (VA system) hospitals, Public Health Service hospitals, and Department of Defense (DoD) military hospitals. The military healthcare system, which is included as part of the government system, is outlined in Table 1.2.

Table 1.2 – Government/U.S. Military Healthcare System

Participants	Physician and nonphysician administrators
	Physicians
	Director of Nursing and other department heads
	Direct care providers
	Regional and national leadership (set policy by service, with guidance from DoD and Congress)
	Regional and national staff experts (implement policy)
Payers	Military hospitals (DoD budget), government insurance plan (CHAMPUS), patients
Payees	Outside contracted providers, military and private hospitals
Mission	Preventive medicine, healthcare delivery (medical and dental) in peace and war, health insurance plan for civilian care when necessary (CHAMPUS)

The key hospital participants with differing roles with respect to technology strategic planning are:

- Administrator (typically a physician at larger hospitals and a nonphysician at smaller ones).
- Physicians.
- Directors of Nursing, logistics (supplies and equipment) and other department heads.
- Other direct care providers.

The local administrative/management team is aided and guided by regional and national leadership and also usually has regional and national staff experts available to consult on a wide variety of healthcare issues.

An example of regional leadership would be major military medical commands that oversee and implement national policy for several hospitals in a given geographic area. An example of national leadership includes the Surgeons General of the military services who, with their staffs, set national policy for their respective services. The Surgeons Gen-

eral act under the guidance of the Assistant Secretary of Defense for Health Affairs, Department of Defense (DoD) for budgeting purposes. All the above leadership act under the guidance, policies, and laws set by the President and Congress. Each of the three services has a national office that assists its hospitals in implementing policy in the area of logistics, which includes medical supplies, facilities, and equipment.

Healthcare system participants are greatly affected by the key payers in the military sector—the federal government through the services (for care directly provided to military beneficiaries), CHAMPUS (the Civilian Health and Medical Program of the Uniformed Services)—a government-funded insurance plan (for civilian care delivered outside the military hospital system), and patients (for care delivered outside the military system without CHAMPUS or with a co-payment for military beneficiaries).

Delivery system payees include both military (DoD) hospitals and outside contracted healthcare providers. DoD hospitals are affected by two major recent actions: (1) the 1991 unification of the three services' hospital budgets into one central DoD Health Affairs Department budget, and (2) an overall decrease in the military—its personnel, budgets, and hospitals in the 1990s. The last action has the effect of causing DoD hospital management to take a closer look at what clinical services they are offering to their active duty people, retired personnel, and families to see how to reduce costs without losing quality. The desire is to provide more clinical services, internally if possible, to reduce CHAMPUS costs. One way to accomplish this is to hire outside contracted providers who then come to DoD hospitals to deliver clinical services.

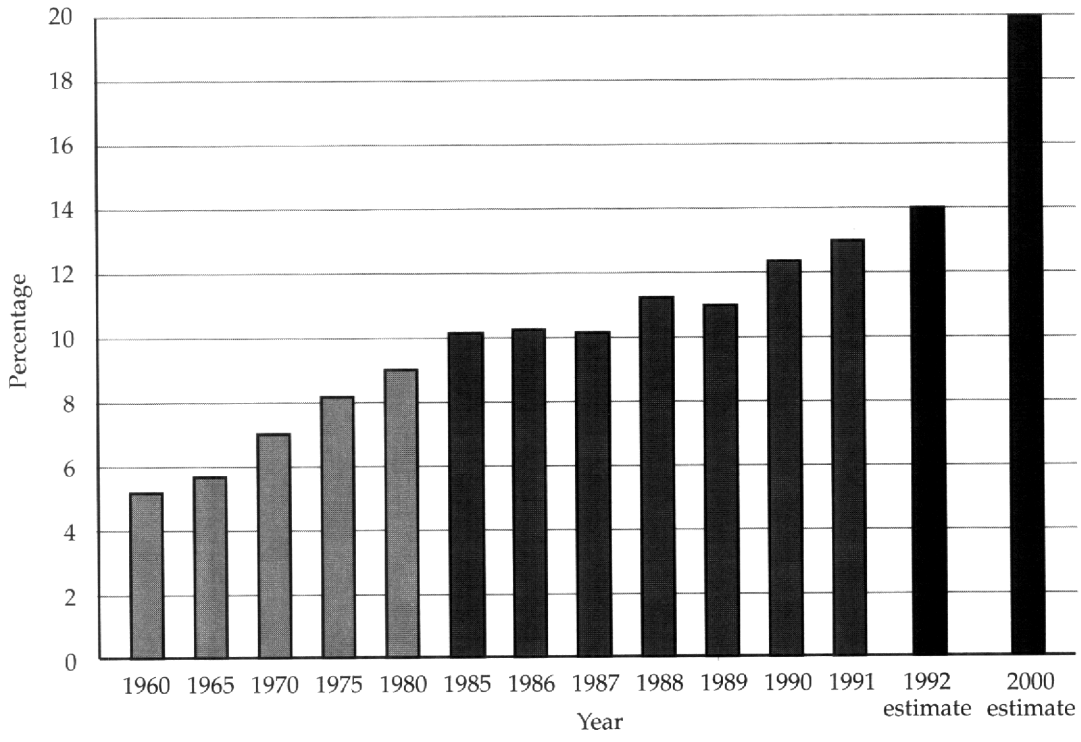
A direct comparison between military and civilian hospitals is difficult to make because of their differing missions. The typical DoD hospital mission is: (1) preventive medicine, (2) primary care—medical and dental, (3) inpatient and outpatient acute healthcare delivery in peace and war, (4) provision of the CHAMPUS health insurance plan, and (5) provision of pharmaceuticals, as appropriate. There were, in 1991, 11 million DoD beneficiaries, 168 hospitals, and more than 500 medical and dental clinics.

1.2.3 Healthcare Delivery System Dynamics

Healthcare delivery dynamics are:

- Impact of technology – Patient care quality and its effectiveness have been significantly improved over the years as a result of technological developments in clinical, information, and telecommunication environments.
- Rise in national spending – Over the past 30 years, federal budget outlays for healthcare services as a percentage of the gross national product (GNP) have been increasing to the present level of approximately 13%, as shown in Figure 1.3.[9]

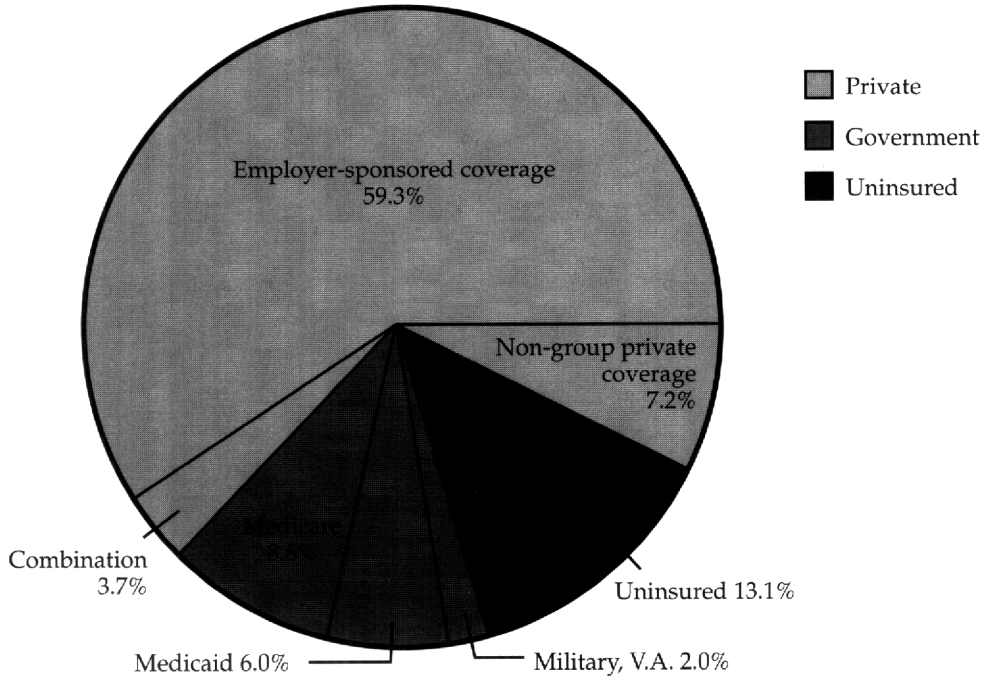
Figure 1.3 – Healthcare spending.



Source: Healthcare Financing Review, 1991.

- How Americans are insured – Services received by various segments of the U.S. population are influenced by their healthcare coverage. About 66% of the population is covered by private health insurance programs. Government programs (including the military, Public Health Service, and the Department of Veterans Affairs) cover about 21%. About 13% of the population is uninsured (see Figure 1.4).[10]

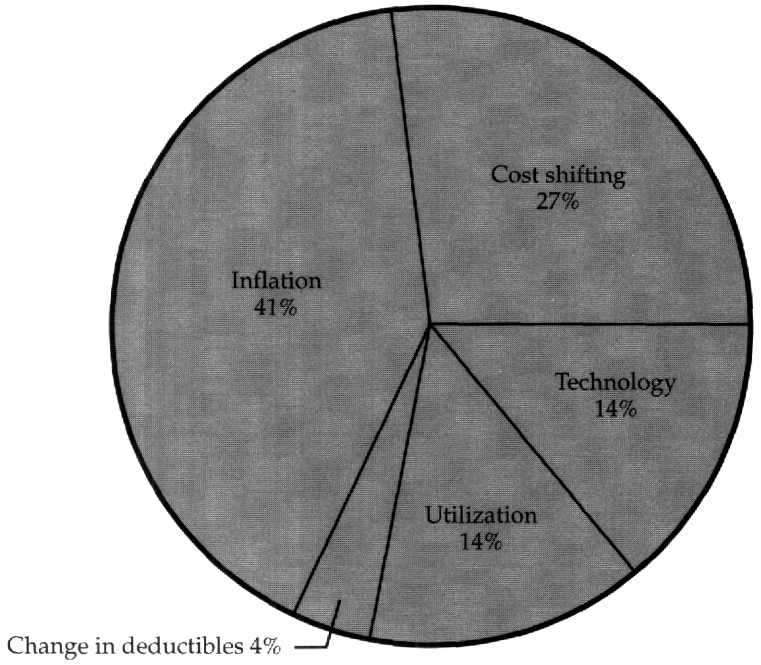
Figure 1.4 – How Americans are insured.



Source: Healthcare Financing Review, 1989.

- Increase in health insurance premiums – A study of the rate of change in private sector (the largest sector) healthcare insurance premiums shows that only 14% of the total increase is directly related to the cost of technology (as shown in Figure 1.5). While this is a small component relative to the total increase, this book offers an understanding of how a technology planning and management program can improve an institution's investment performance.

Figure 1.5 – Reasons why private health insurance premiums have increased.



Source: Hewitt Associates; Modern Healthcare, Nov. 12, 1990.

- What healthcare payers are buying – While hospitals have predominantly been the center of technology-based healthcare services, it is the technology that facilitates the capability to increase quality and quantity of healthcare services offered outside the hospital (e.g., imaging centers, emergency clinics, homes, etc.). Yet hospital care constitutes the single largest component, approximately 40% of total healthcare outlays. Outlays for construction and administration account for an additional 12%.[11] The rate of change of hospital services expenditures expressed on a per capita basis, as shown in Figure 1.6b, illustrates that these services are being subjected to a stronger pressure to optimize operations than are nonhospital services.

- How Americans are insured – Services received by various segments of the U.S. population are influenced by their healthcare coverage. About 66% of the population is covered by private health insurance programs. Government programs (including the military, Public Health Service, and the Department of Veterans Affairs) cover about 21%. About 13% of the population is uninsured (see Figure 1.4).[10]

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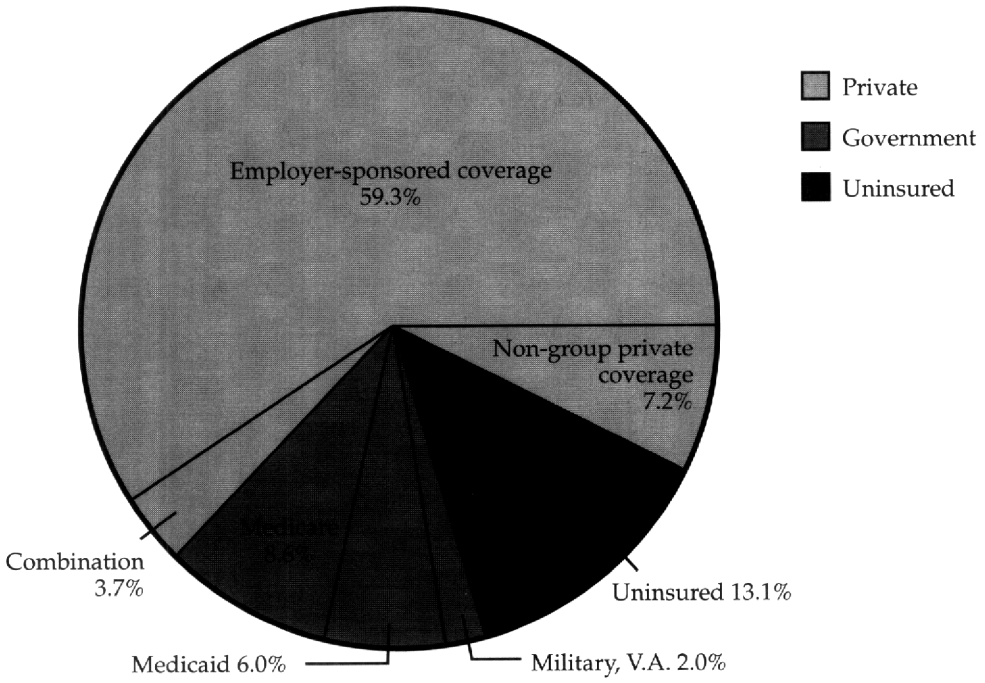

Source: Healthcare Financing Review, 1989.

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the hospital equipment budget, with almost half of surveyed officers believing that this figure will climb in the next 2 years.[4] Equipment growth will be further magnified as the point-of-care for specific patient populations starts to shift toward freestanding and mobile healthcare facilities.

Table 1.3 – Capital/Total Cost and Capital Operating Cost Ratios 1980–1990 (annual percentage change)

Year	Capital/ Total Costs	Annual Percent Change	Capital Operating Cost	Annual Percent Change
1980	6.2%	–1.6%	6.6%	-1.5%
1981	6.3	1.6	6.7	1.5
1982	6.5	3.2	7.0	4.5
1983	6.9	6.2	7.4	5.7
1984	7.9	14.5	8.6	16.2
1985	8.3	5.1	9.1	5.8
1986	8.4	1.2	9.2	1.1
1987	8.5	1.2	9.3	1.1
1988	8.5	0.0	9.3	0.0
1989	8.5	0.0	9.3	0.0
1990	8.4	–1.1	9.2	–1.2

Source: Pro Pac Analysis of American Hospital Association National Hospital - Panel Survey, 1991.

1.3 *Trends and Directions in Healthcare Delivery*

The healthcare delivery system in general, and the practice of modern diagnostic and interventional medicine in particular, are impacted by a continuous process of technological evolution. This process incorporates a wide variety of services and programs. From home-care services on one end of the spectrum to multi-organ transplant programs on the other, changes in the state-of-the-art are leading to an increased dependence on the use of instrumentation in the delivery of patient care.

There are abundant examples that demonstrate how modern medicine is utilizing new instruments to extend powers of observation, manipulation, and control. In a way, better technology can be viewed in terms of its contribution to the prevention, detection, analysis, and treatment of diseases, in terms of increasing life expectancy and quality, in

terms of preventing premature death, in terms of promoting access to care, and in terms of increasing efficient use of resources.[12]

In this environment of increased offering and utilization of instrumentation, a commitment by healthcare technology professionals to the protection of public health is a fundamental canon. Evolving alongside technological diffusion is the responsibility that each clinical engineer and healthcare technology manager bears as a professional schooled in the engineering and sciences disciplines.[13] The application of these skills in the clinical environment can ensure that the planning of deployment of medical technology will improve the quality of patient care and help contain costs.

How have these trends and directions affected hospitals? In the near-term, they have been translated into healthcare delivery system pressures that mold and shape strategic planning for technology. Because of the wide variance in the U.S. between types of hospitals and their various missions, we will analyze system pressures for a sample subset of U.S. hospitals, i.e., the private, for-profit multihospital system. This analysis is intended to serve as an example of the effect of the changing healthcare environment on hospitals. Healthcare technology managers may want to compare these pressures and their effects to those experienced by their own hospitals.

1.3.1 Major Healthcare Trends and Directions

Major healthcare trends and directions are:

- The location and design of treatment areas are changing within the hospital, as free-standing and mobile treatment sites are evolving.
- Healthcare benefits, coverage, choices, and costs are continuing to evolve.
- Hospitals are being subjected to more pressure to manage costs.
- Hospitals are treating older adults and younger prematurely born infants, both groups having higher acuity level.
- The job structure of hospitals and the demand for skilled labor is changing.
- Hospitals need to maintain a strong cash flow to support construction, medical equipment acquisitions, and to expand information systems.
- Hospitals are facing increasing competition related to technology.

- Information systems that more effectively integrate clinical and business issues for hospitals are needed and will be developed.
- Changes in reimbursement policies are contributing to a decrease in technology-related offerings and to an increase, therefore, in the expected life-cycle of existing technologies.
- In their search for efficiency, hospitals are focusing on the integration of all technologies and modalities of care to avoid duplication and inappropriate utilization of resources.
- Hospitals are developing technology planning and management programs to guide their decisions because limited resources are being subjected to competing demands, thus requiring more carefully executed plans.
- Hospitals are creating technology planning teams to coordinate the absorption of new and replacement technologies that can contribute to a cost-effective delivery of quality care; these teams may also suggest changes in the current delivery system.
- Hospital maintenance costs are emerging as a significant expense item; controlling and managing these expenses will continue to be a significant issue for in-house clinical engineering departments.

1.4 *Healthcare Delivery System Pressures*

The pressures on the healthcare delivery system include: society's expectations, economic conditions, the legal justice system, regulations, ethics, and technology. Societal expectations for private hospitals, to some degree, are shaped by the hospital's size and location. The small rural hospital is viewed by its patients differently than the suburban community's medical center. However, on average, the relatively small private rural hospitals in multihospital systems tend to be very competitive and successful in their local areas, as are their larger suburban counterparts. Both are typically smaller and more streamlined than their public hospital competitors. And both are expected to provide the highest quality care at the lowest reasonable price, where quality is a function of personnel, facilities, technology, and clinical procedures offered.

Economic pressures for private sector hospitals are driven by Diagnosis Related Group (DRG) and related reimbursement criteria. The margin-driven multihospital system responds to this pressure by utilizing the capabilities and the expertise of its central headquarters to help local hospitals optimize purchasing, maximize reimbursement, and make the best use of management information with linked information systems.

Legal pressures on the private sector result primarily from professional malpractice and dealing with federal and state governments as major clients. Malpractice for the multihospital system can particularly be a problem because of a "deep pockets" perception of these corporations. Dealing with the government as a major client (Medicare and certain state programs) affects the multihospital system not only in its reimbursement for patient care but also in tax issues, how it must report its activities to others, and other business practices.

Besides the typical regulatory pressures that all hospitals face, multihospital systems usually operate in several states and often provide more types and levels of care. This adds greater complexity to their management decision-making, although central resources are available to deal with these issues. Medical equipment-related regulatory pressures are particularly difficult because they are applied to a heavily regulated industry that must compete in the free market. These pressures encompass many technology-related standards including the reporting requirements of the Safe Medical Devices Act of 1990. Another regulatory pressure recently emphasized is that of credentialing, especially credentialing associated with the use of medical technology. Regulations are rapidly changing and the technology manager needs to realize this and maintain a good knowledge of regulatory issues.

Technological pressures on the profit-driven multihospital systems result from the hospitals' desire to have different technologies available so they can be competitive in their local community with respect to attracting patients and physicians. The composition of these technologies are a function of the hospital's size, location, budget, and mission in a given community. These hospitals may have certain opportunities in purchasing technology, such as more flexibility of terms and better pricing, because of volume purchases. Therefore, they should assess and manage their technological needs to take advantage of these opportunities.

1.5 *Summary*

In order to add value to their hospitals, healthcare technology managers must understand the scope and content of technology planning and management programs. The information offered throughout this book will help managers understand the various processes involved in these programs. In order to become a more effective technology manager we suggest reading this book and then:

- Become involved in technology planning and management programs in your hospital. Be prepared to commit yourself to expanding your professional credibility and to assuming new responsibilities.
- Gain an understanding of the pressures on the healthcare delivery system, their influence on hospital operations, and how technology can improve outcomes of care, reduce cost, and/or enhance quality of life for patients.
- Educate other key healthcare professionals on how to demonstrate the value of individual technologies through analysis of each technology from financial, engineering, quality of care, and management perspectives.

2.0 STRATEGIC TECHNOLOGY PLANNING

In response to the various pressures described in the preceding section, some private sector hospitals have adopted a strategic technology planning process that helps them address the issues they face. An example of this process and the role of healthcare technology managers is presented in this section. Information in this section represents a blend of the experiences of the authors and processes described by ECRI in references 6, 14, and 15.

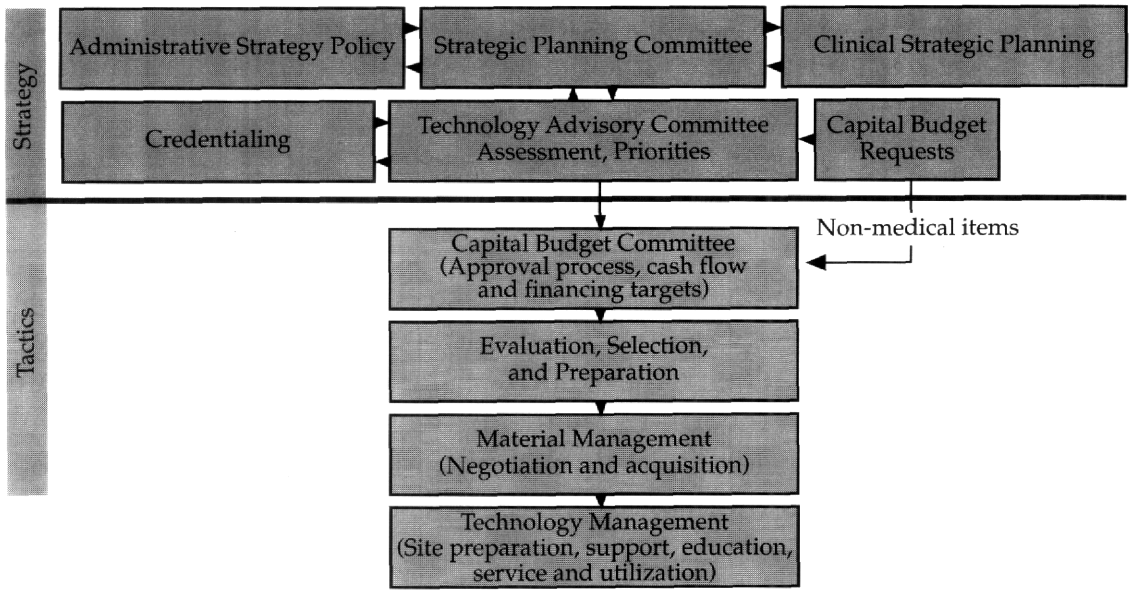
2.1 *Strategic Planning Process*

Leading private hospital systems have begun to combine strategic technology planning with other technology management activities in a program that effectively integrates new technologies with the hospitals' existing technology base. This has resulted in high quality care at reasonable cost. Among those who have been its leading catalysts, ECRI (formerly the Emergency Care Research Institute) is known for articulating this program and encouraging its proliferation initially among regional healthcare systems and now for single or multihospital systems as well.[14]

A modified version of ECRI's program is diagrammed in Figure 2.1.[15] Key program components include clinical strategic planning, technology strategic planning, technology assessment, interaction with capital budgeting, acquisition and deployment, resource (or equipment assets) management, and monitoring and evaluation. The significance of the first two components is that a technology strategic plan is derived from

and supports a well-defined clinical strategic plan. These components and the one dealing with capital budgeting will be analyzed in this section. The remaining components will be analyzed in Sections 3, 4, and 5.

Figure 2.1 – Principles and practices of medical technology management.



2.1.1 Clinical and Technology Strategic Plan

Usually considered long-range and continually evolving, a clinical strategic plan is updated annually. For a given year, the program begins when key hospital participants, through the strategic planning process, assess what clinical services the hospital should be offering in its referral area. They take into account healthcare trends, demographic and market share data, and space and facilities plans. They analyze their facility's strengths and weaknesses, goals and objectives, competition, and existing technology base. The outcome of this process is a clinical strategic plan that establishes the organization's vision for the year and referral area needs and the hospital's objectives in meeting them.

It is not possible to adequately complete a clinical strategic plan without engaging in the process of strategic technology planning. A key role for technology managers is to assist their organization throughout the combined clinical and technology strategic planning processes by

matching available technical capabilities, both existing and new, with clinical requirements. To accomplish this, technology managers must understand why their institutions' values and mission are set as they are, pursue their institutions' strategic plan through that knowledge, and plan in a way that effectively allocates limited resources. Although a technology manager may not be assigned to develop an institution's overall strategic plan, they must understand and believe in it in order to offer good input for hospital management. In providing this input, there are several things the technology manager can do:

- Determine how the hospital's technological deployment should be evaluated.
- Assist in providing a review of emerging technological innovations and determining the impact they can have on the hospital. This is facilitated by having good rapport with the research and development industry.
- Articulate justifications and provisions for adoption of new technologies or enhancing existing ones.
- Because tomorrow's clinical devices are in the research laboratories today, consider visits to such sites as well as to the exhibit areas at major medical and scientific meetings.
- Be familiar with the institution and its equipment users' ability to assimilate new technology.

The past decade has seen a trend toward increased legislation and federal regulation in healthcare. These and other pressures require that additional or replacement medical technology be well-anticipated and justified. The tool Texas Children's Hospital uses as a rationale for technology adoption is as follows:

- Clinical Necessity
  - Meet/exceed medical standard of care.
  - Impact care quality or level.
  - Impact life quality.
  - Improve intervention's accuracy, specificity, reliability, and/or safety.
  - Increase rate of recovery.
  - Community needs or desires.
  - Change in service volume or focus.

- Management Support
  - More effective care plan and decision-making processes.
  - Improve operational efficiency and effectiveness.
  - Improve offering of current service or development of new service programs.
  - Decrease liability/risk exposure.
  - Increase compliance with regulations.
  - Reduce dependence on user skill level.
  - Improve departmental support.
  - Increase clinical proficiency.
- Market Preference
  - Improve access to care.
  - Increase customer convenience and/or satisfaction.
  - Improve organization/service image.
  - Improve financial position and market share.
  - Decrease cost of adoption and ownership.
  - Increase return on investment.

2.2 *Technology Strategic Planning Process*

2.2.1 Establish a Medical Technology Advisory Committee

When annual clinical strategic planning has started and hospital leaders have begun to analyze or reaffirm what clinical services they want to offer the community, the hospital can then conduct credible technology strategic planning. Key elements of this planning involve an initial audit of existing technologies, conducting a technology assessment of new and emerging technologies for fit with current or desired clinical services, plan for replacement and selection of new technologies, setting priorities for technology acquisition, and developing a process to implement equipment acquisition and monitor ongoing utilization. "Increasingly, hospitals are designating a senior manager (e.g., an administrator, the director of planning, the director of clinical engineering) to take the responsibility for technology assessment and planning. That person should have the primary responsibility for developing the strategic technology plan with the help of key physicians, department managers, and senior executives."[6]

Hospitals can form a Medical Technology Advisory Committee (MTAC), overseen by the designated senior manager and consisting of

the type of members mentioned above, to conduct the strategic technology planning process, and to annually recommend technology priorities to the hospital Strategic Planning Committee and Capital Budget Committee (see Figure 2.1). It is important to involve physicians and nurses in this process.

2.2.2 Conduct an Initial Technology Audit

In the initial technology audit, each major clinical service or product line must be analyzed to determine how well the existing technology base supports it. The audit can be conducted along service lines (e.g., radiology, cardiology, surgery) or technology function (e.g., imaging, therapeutic, diagnostic). This audit can be best achieved by an ad hoc team approach, utilizing designated physicians, department heads, and technology managers. The key audit activities are as follows:[15]

- Develop a complete hospital-wide assets inventory, e.g., quantity and quality of equipment included. Compare the existing technology base against known and evolving standards-of-care information, patient outcomes data, and known equipment problems.
- Collect and review information on technology utilization; assess appropriate use, opportunities for improvement, and risk level.
- Review technology users' education needs as they relate to the application and servicing of medical equipment; include physicians, nurses, technologists, and support staff.
- Credential users for competence in the application of new technologies: assess needs, whether requirements are being met, and what risks are involved (credentialing committees will be the primary group to match clinician skills with evolving clinical treatment procedures or protocols).
- Keep up with published clinical protocols and practice guidelines using available healthcare standards directories.
- Utilize clinical outcomes data for quality assurance (QA) and risk management program feedback.

2.2.3 Conduct Ongoing Technology Assessment

While it is not expected that every hospital will have all the required expertise in-house to conduct the initial technology audit or ongoing technology assessment, the execution of this planning process is sufficiently

critical for a hospital's success that outside expertise should be obtained when necessary. The audit will allow the gathering of information about the status of the existing technology base, and should enhance the capability of the MTAC to assess the impact of new and emerging technologies on their major clinical services. In a typical technology assessment (conducted throughout the year, but reviewed during the MTAC's annual involvement in the capital budgeting process), the following issues should be considered:[14]

- Needs (including utilization rate of current equipment and of new equipment).
- Value of the technology.
- Technical validity and maturity.
- Ability to assimilate and to maintain the technology.
- Medical and other staff satisfaction.
- Impact on staffing and delivery of care.
- Impact on facilities and code compliance.
- Impact on standards of care and quality.
- Economic considerations (e.g., reimbursement, life-cycle costs).

The committee should meet often enough to continue the assessment process as needed.

2.2.4 MTAC Involvement in Budgeting

All of the information collected above (technology audit results and technology assessments) will be utilized in developing budget strategies. Budgeting is part of strategic technology planning in that a 2 to 5-year long-range capital spending plan should be created. This is in addition to the annual capital budget preparation that addresses 1 year at a time. The MTAC should provide key information regarding capital budget requests and make recommendations to the Capital Budget Committee each year.

The MTAC will recommend priorities for replacement and for new and emerging technologies that, over a period of several years, will guide the acquisitions that provide the desired service developments or enhancements. Priorities will be recommended on the basis of need, risk, cost (acquisition, operational, and maintenance), utilization, and fit with the clinical strategic plan.

Following is an example of a method used by private hospitals to solicit and review technology requests and then to use the recommendations of the MTAC in capital budgeting:

- Utilizing an accurate computerized inventory of department medical devices (typically provided by clinical engineering), the department head sorts the inventory by equipment classification and rates it on the basis of the following factors: identifiers—system name; manufacturer; model; costs (purchase price, maintenance costs); age; remaining useful life; utilization; reliability; and risk (meeting standard of care).
- With rated inventory in hand, the department head can develop a suggested 2 to 5-year capital equipment plan by answering the following questions and using assessment information from the MTAC:
  - What do I need? Includes upgrades, additions, replacements (requires cost and features information).
  - Why do I need it? Utilize Capital Budget Request form (see Figure 2.2); do Capital Incremental Financial Analysis only for items over $50,000 (see Figure 2.3); do Life-Cycle Cost (LCC) analysis for requests over $100,000.
  - How do I prioritize? Based on the goals set by the clinical and technology strategic plans for individual departments, capital item requests are rated on a scale that includes the following factors: risk and safety, new clinical service, clinical and technical obsolescence, economic considerations (projected costs and revenues, costs of maintenance and repair), and standardization.

Hospital-wide information as described above is reviewed by the MTAC which develops a means of judging each technology request on its individual merits. At least three indicators should be used:

- Projected cost and revenue figures for technology requests should be compared hospital-wide to determine what should be done now versus in later years.
- Requests should be compared hospital-wide for assessment of interchangeability, standardization, and possible redeployment.
- Overall ratings from above should be compared.

Figure 2.2 – Capital Budget Request form.

CAPITAL BUDGET REQUEST

Request No. _____ Date: _____

Department Name: _____ Department No. _____

Item: _____ Priority No. _____

Facility/Location: _____

Impact on Facility: _____

Cost Estimate: _____ Quote Attached: _____

Classification:

__ Replacement	__ Maintenance	__ Emerging technology
__ Cost reduction	__ Expansion	__ New service
__ Service improvement	__ Patient safety	__ Standard of care
__ JCAHO recommended	__ Current lease	__ Other

Justification:

1. Description of item, purpose, and function.
2. Reason for purchase, alternative, consequence of not purchasing.
3. Trade-in issues, if appropriate: what trade-in, age of trade-in, amount of credit given.
4. Expected useful life of item.
5. Projected utilization of item.
6. Desired month of purchase of item and why.
7. Effect of purchase on this department and other departments.

Figure 2.3 – Request for Capital Incremental Financial Analysis form.

Request for Capital Incremental Financial Analysis
(EBDIT = Earnings before depreciation, interest or taxes)

Project: _____

Year	1	2	3	4	5	5 Year Total
Increm. Increase in Procedure						
Increm. Gross Revenue Impact						
Revenue Deductions						
Increm. Net Revenue Impact						
Increm.Operating Expenses Impact						
Salaries						
Benefits						
Supplies						
Maintenance						
Other						
Bad Debt						
Total						
Total Increm. Impact of EBDIT						
EBDIT Profit Impact						
+ After–Tax Proceeds from Sale of Assets*						
– Capital Expenditures						
Adjusted Cash Flow Impact						
Present Value Factor						
Present Value						
Total NPV Avg. EBDIT Return on Investment						

* if applicable

The results of this analysis will be prioritized recommendations for the coming year (as well as for years 2 to 5 in the future) that are sent to hospital management and the Capital Budget Committee from the MTAC.

There is a three-fold purpose for the capital budgeting process:[14]

- To develop procedures to solicit and review technology requests (initiated by the Capital Budget Committee, but analyzed by the MTAC).
- To coordinate capital expenditures with available resources (done by the Capital Budget Committee).
- To determine optimal financing methods for acquisition (done by the Capital Budget Committee).

As a last step, the Capital Budget Committee, or a designated ad hoc team from materials management and clinical engineering, is appointed to review the final capital budget listing to recommend when the items should be purchased during the next year and, if possible, to determine if there should be negotiated, centralized, and coordinated acquisition processes planned for similar items from different departments. Determination of optimal financing methods for technology acquisition are discussed in Section 5.

The aggregate effect of this program will be clearly demonstrated in the hospital's overall strategy and its desire for continuous quality improvement.

2.2.5 Sample Strategic Technology Plan

(Note: With the permission of ECRI this section is reprinted from reference 6.)

"Tables 2.1 through 2.4 illustrate portions of the work product characteristics of strategic technology planning for an entire hospital. Please note that the sample in each table comes from an actual strategic plan from one of four different hospitals; data in one table does not relate to data in another.

One aspect of strategic technology planning is determining the technology needs of each unit in an institution. Table 2.1 illustrates the technology needs of a hospital's critical care units. The estimated cost of each technology is noted, as is the priority for acquiring it immediately.

Table 2.1–Technology Needs for Critical Care Units, Hospital A

Need	Estimated Cost	Priority
Acquire 12-channel dedicated telemetry unit monitoring system	$120,000	High
Upgrade CCU monitors (arrhythmia)	$48,000	Medium
Replace existing monitors in anesthesia	$100,000	Medium
Acquire monitors (short procedure) (recovery)	$120,000	Medium
Standardize defibrillators/monitors	$50,000	Medium
Determine cost-effectiveness of continued use of disposable pressure transducers	Unknown	Medium
Add monitors to emergency department	$25,000	Low
Replace existing monitors in NICU	$100,000	Low
Acquire oxygen monitors for infant ventilators ($1,000 each)	$8,000	Medium

Source: ECRI, Capital, Competition, and Constraints: Managing Healthcare in the 1990s; A Guide for Hospital Executives, 1992.

Table 2.2 shows the stage where greater detail can be incorporated. Specific equipment and its cost are determined for each critical care unit in the hospital; acquisition is intended for a specific fiscal year. Note that the plan indicates the relocation and repair of existing equipment — also a part of strategic technology planning.

Table 2.2–Technology Needs for Critical Care Units, Hospital B

Area	Need	Cost
3E Pulmonary ICU	Purchase five-bed monitoring system	$117,000
	Relocate defibrillators from hospital F	$0
3E Pulmonary Stepdown	Purchase 10-bed monitoring system with telemetry transmitter	$171,000
4E Neuro ICU	Purchase five-bed monitoring system	$117,000
	Relocate defibrillator from the emergency room	$0
4 Neuro Stepdown	Purchase 10-bed monitoring system	$171,000
Emergency Room	Purchase eight-bed monitoring system with two telemetry modules to transmit to central station	$135,000
	Purchase transcutaneous pacer for Trauma 1 and Trauma 2	$8,500
	Purchase three defibrillator/monitors-one with pacing (two for adult crash carts and one for pediatric crash cart)	$25,500
	Repair defibrillator	$0
	Relocate defibrillator	$0
	Relocate defibrillator to SE	$0
	Relocate defibrillator to surgery	$0
	Relocate defibrillator to anesthesia	$0

Source: ECRI, Capital, Competition, and Constraints: Managing Healthcare in the 1990s; A Guide for Hospital Executives, 1992.

Table 2.3–Technology Needs for Fiscal Year 1991-1992 for All Departments, Hospital C

Need	Cost
Radiology and Diagnostic Imaging	
• Acquire new CT scanner to replace existing unit	$950,000-$1,100,000
• Decommission one of the R/F rooms	$0
Subtotal	$950,000-$1,100,000
Anesthesia Services	
• Purchase automated recordkeeping/quality assurance/communication network to link outside anesthesia group with hospital	$100,000
• Acquire transesophageal echocardiography (TEE) system for open-heart surgery	$150,000-$225,000
• Purchase EEG/evoked-potential monitoring for use in carotid procedures	$20,000
• Purchase four new anesthesia machines for OR expansion project	$120,000
Subtotal	$390,000-$465,000
Laser Technology	
• Allow contingency for investigating feasibility of acquiring a multispecialty argon, Nd:YAG, Co_2, or KTP laser	$100,000
Subtotal	$100,000
Cardiology	
• Upgrade 12-lead ECG system to perform late potential analysis	Unknown
Subtotal	Unknown
Respiratory Therapy	
• Overhaul or upgrade ventilators to allow for pressure support ventilation ($2,000 or $7,000 each)	$30,000
Subtotal	$30,000
Clinical Laboratory	
• Purchase chemistry analyzer	$65,000-$85,000
• Pursue the possibility of providing consultation services to local physician offices for compliance with CLIA '88	
• Begin to acquire in-house laboratory equipment servicing capability	
Subtotal	$68,000-$85,000
Subtotal Fiscal Year 1991-1992	$11,538,000-$1,780,000
Contingency (10% of equipment acquisition costs)	$153,800-$178,000
Total Fiscal Year,1991-1992	$11,691,800-$1,958,000

Source: ECRI, Capital, Competition, and Constraints: Managing Healthcare in the 1990s; A Guide for Hospital Executives, 1992.

After priorities for equipment acquisition *within* each department or service are determined, priorities *among* all departments or services are weighed and a master plan is constructed. Table 2.3 shows the acquisition requests from the various hospital departments competing for technology resources.

A master plan provides senior hospital executives and trustees the information to understand the direction of their institution and its future financial and service commitment. Table 2.4 summarizes proposed equipment acquisitions by service and by fiscal year."[6]

Table 2.4–Summary of Expenditures by Service and by Fiscal Year, Hospital D

Service/Technology	1991-1992	1992-1993	1993-1994	1994-1995	1995-1996 (incomplete)
Radiology and Diagnostic Imaging	$1,920,000	$3,950,000	$1,835,000	$1,230,000	-
Radiology Oncology	-	-	-	-	-
Critical Care	$76,500	$17,000	$355,300	$975,000	$600,000
Infusion Technology	-	-	$750,000	-	-
Anesthesia Technology	$535,000	$670,000	-	-	-
Laser Technology	$110,000	$325,000	$150,000	-	$300,000
Cardiology	$100,000	$250,000	$500,000	$400	-
Rehabilitation Services	-	-	-	-	-
Respiratory Therapy	$120,000	$30,000	-	-	-
Clinical Laboratory	$165,000	$77,000	$155,000	$37,000	-
Subtotal	$3,026,500	$5,319,000	$3,745,300	$2,942,000	$600,000
Contingency (10% of subtotal)	$302,650	$531,900	$374,530	$294,200	$60,000
Total	$3,329,150	$5,850,900	$4,119,830	$3,236,200	$660,000

Source: ECRI, Capital, Competition, and Constraints: Managing Healthcare in the 1990s; A Guide for Hospital Executives, 1992.

2.3 Role of Technology

Medical technology contributes to the prevention of diseases by protecting against or reducing the risk of its occurrence as well as limiting its impact. It helps clinicians screen abnormalities and the risk associated with these. It contributes to the diagnosis of clinical signs for the purpose of identifying the nature or the cause or the extent of the pathological event.[16] It contributes to treatment by restoring, improving, and replacing bodily function as well as preventing further deterioration or pain. It contributes to rehabilitation by restoring, replacing, improving, or maintaining physical or mental function impairment.

Technology is expected to reduce the risk of a disease, shorten illness duration, improve the quality of care, increase access to care, and replace or limit the decay of a person's function. In addition, technology is expected to contain cost and improve intervention risk management. Acquisition of technology is accomplished for a number of reasons:

- To provide needed services in the community.
- To improve diagnostic and therapeutic efficiency.
- To increase the hospital's cost-effectiveness.
- To reduce risk exposure.
- To attract high quality physicians.
- To expand the referral base or better serve the primary referral base.

Technology plays a major role in supporting the hospital's strategic plan and typically is expected to have less than a 5-year payback. (The exception is when technology is used to attract a physician, whose anticipated referral base will significantly overcome losses from supporting technology investments.) The investment in technology often is a key factor in feasibility studies conducted to determine whether new clinical services should be offered or existing ones enhanced. Techniques that can increase throughput and utilization and maximize current assets are routinely sought. Strategies that increase reliability and minimize equipment downtime have been demonstrated to substantially affect any healthcare organization's bottom line.[17]

2.4 Summary

Using the tools discussed in this section, the technology manager can make a significant contribution toward the preparation and implementation of a strategic technology plan. To accomplish this, take the following steps:

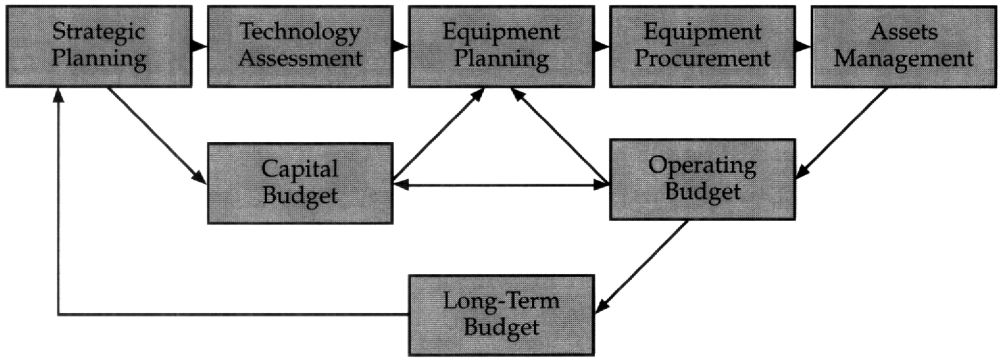
- Determine the status of your hospital's technology planning and management program. Establish new goals (if appropriate) for the program.
- Establish with hospital administration your involvement in this program's integration into the existing hospital strategic planning process.

- Ensure that you understand your hospital's capital budget process and its methods for allocating monies for funding of medical technology.
- Assist in forming an MTAC, with representation from key clinical services, administration, and finance.
- Conduct technology audits by service line and/or by technology function. Compare your hospital's strengths and weaknesses with other similar hospitals.
- Determine life-cycle costs of key selected devices from your medical equipment inventory.
- Adapt the process and forms described in this section to suit your hospital's environment.
- Be prepared to participate in different user task forces that focus on studying the value of individual technologies and report their findings back to the MTAC.

3.0 TECHNOLOGY ASSESSMENT

As medical technology continues to evolve, so does its impact on patient outcome, hospital operations, and financial resources. The ability to manage this evolution and its subsequent implications has become a major challenge for all healthcare organizations. Successful management of technology will ensure a good match between needs and capabilities, and between staff and technology. To be successful, an ongoing technology assessment process must be an integral part of an ongoing technology planning and management program at the hospital, addressing the needs of the patient, the user, and the support team (Figure 3.1). This will facilitate better equipment planning and utilization of the hospital's resources. The manager who is knowledgeable about the organization's culture, equipment users' needs, the environment within which equipment will be applied, equipment engineering, and emerging technological capabilities will be successful in implementing and managing technological changes.[18]

Figure 3.1 – Technology planning and management program.



It is in the technology assessment process that the clinical engineering/technology management professional needs to wear two hats: that of the manager and that of the engineer. This is a unique position, requiring expertise and detailed preparation, that allows one to be a key leader and contributor to the decision-making process of the Medical Technology Advisory Committee (MTAC).

The MTAC utilizes an ad hoc team approach to conduct technology assessment of selected services and technologies throughout the year. The ad hoc teams may incorporate representatives of equipment users, equipment service providers, physicians, purchasing agents, reimbursement managers, administration, and other members from the institution as applicable.

3.1 *Prerequisite for Technology Assessment*

Medical technology is a major strategic factor in positioning and creating a positive community perception of the hospital. Exciting new biomedical devices and systems are continually being introduced. And, they are introduced at a time when the pressure on hospitals to contain expenditures is mounting. Therefore, forecasting the deployment of medical technology and the capacity to continually evaluate its impact on the hospital require that the hospital be willing to provide the support for such a program. (Note: Many organizations are aware that an in-house "champion" is needed to provide leadership that continually and objectively plans ahead. The champion and the program being championed may use additional in-house or independent expertise as needed. To get focused attention on the technology assessment function and this program in larger academically-affiliated and government hospitals, the

position of a chief technology officer (CTO) is being created.) Traditionally, executives rely on their staff to produce objective analyses of the hospital's technological needs. Without such analyses, executives may approve purchasing decisions of sophisticated biomedical equipment only to discover that some needs or features were not included with this installation, or that those features are not yet approved for delivery, or that the installation has not been adequately planned.

Many hospitals perform technology assessment activities to project needs for new assets and to better manage existing assets. Because the task is complex, an interdisciplinary approach and a cooperative attitude among the assessment team leadership is required. The ability to integrate information from disciplines such as clinical, technical, financial, administrative, and facility in a timely and objective manner is critical to the success of the assessment. This section emphasizes how technology assessment fits within a technology planning and management program and recognizes the importance of corporate skills in forecasting medical equipment changes and determining the impact of changes on the hospital's market position. Within the technology planning and management program, the focus on capital assets management of medical equipment should not lead to the exclusion of accessories, supplies, and disposables also required.

Medical equipment has a life-cycle that can be defined as (1) the innovation phase, which includes the concept, basic and applied research, and development, and (2) the adoption phase, which begins with the clinical studies, through diffusion, and wide-spread use (Figure 1.1). These phases are different from each other in the scope of professional skills involved, their impact on patient care, compliance with regulatory requirements, and the extent of required operational support. In evaluating the applicability of a device or a system for use in the hospital, it is important to note in which phase of its life-cycle the equipment currently resides.

3.2 *Technology Assessment Process*

More and more hospitals are faced with the difficult phenomena of a capital equipment requests list that is much larger than their capital budget allocation. The most difficult decision, then, is the one that matches clinical needs with financial capability. In doing so, the following issues are often raised: how to avoid costly technology mistakes; how to wisely target capital dollars for technology; how to avoid medical staff conflicts

as they relate to technology; how to control equipment-related risks; and how to maximize the useful life of the equipment or systems while minimizing the cost of ownership. A hospital's clinical engineering department can assist in providing the answers to these questions.

As mentioned earlier, technology assessment is a component of technology planning that begins with the analysis of the hospital's existing technology base. It is easy to perceive then that technology assessment, rather than an equipment comparison, is a new major function for a clinical engineering department.[19] It is important that clinical engineers be well prepared for the challenge. As discussed in Section 2, they must have a full understanding of the mission of their particular hospitals, a familiarity with the healthcare delivery system, and the cooperation of hospital administrators and the medical staff. To aid in the technology assessment process, clinical engineers need to utilize the following tools: (1) access to national database services, directories, and libraries; (2) visits to scientific and clinical exhibits; (3) a network with key industry contacts; and (4) a relationship with peers throughout the country.[20]

The need for clinical engineering's involvement in the technology planning and management program becomes evident when the problems cited below are repeatedly encountered:

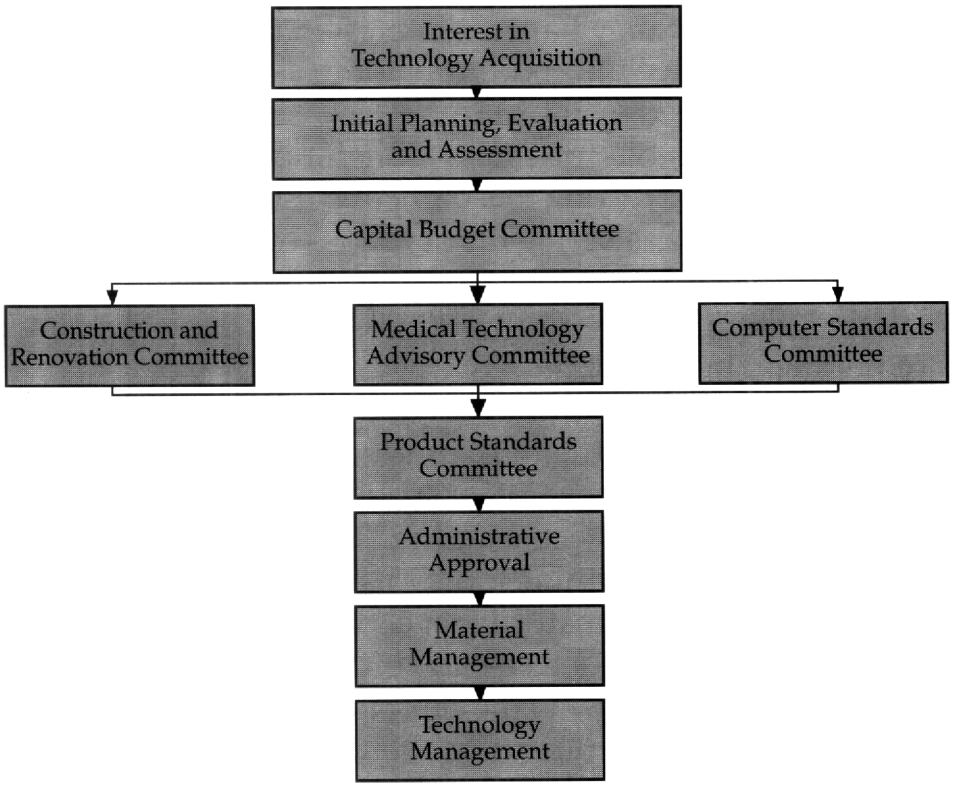
- Recently purchased equipment or its functions are underutilized.
- Ongoing user problems with equipment.
- Excessive equipment maintenance costs.
- Inability to comply with standards or guidelines (e.g., JCAHO requirements) for equipment management.
- High percentage of equipment awaiting repair.
- Equipment operator training inefficiency due to shortage of allied health professionals.

A closer look at the symptoms behind these problems may reveal the following:

- A lack of a central clearinghouse to collect, index, and monitor all technology-related information for future planning purposes.
- The absence of procedures for identifying emerging technologies for potential acquisition.

- The lack of a systematic plan for conducting technology assessment, resulting in the inability to maximize the benefits from deployment of available technology.
- The inability to benefit from the organization's own previous experience with a particular type of technology.
- The random replacement of medical technologies, rather than a systematic plan based on a set of well-developed criteria.
- The lack of integration of technology acquisition into the strategic and capital planning of the hospital.

Figure 3.2 – Technology assessment process.



To address these issues, a technology assessment process was initiated at one leading private hospital with the following objectives: (1) accumulate information on medical equipment, (2) facilitate systematic planning, (3) create an administrative structure supporting the assessment process and its methodology, (4) monitor the replacement of outdated technology, and (5) improve the capital budget process by focusing on long-term needs relative to the acquisition of medical equipment.[21]

The process, in general, and the collection of up-to-date pertinent information, in particular, require the expenditure of certain resources and the active participation of designated hospital staff in networks providing technology assessment information. For example, corporate membership in organizations and societies that provide such information should be considered, as well as subscriptions to certain computerized databases and printed sources.[22]

At the example hospital, an MTAC was formed to conduct technology assessment. It is chaired by the Director of Clinical Engineering. Other managers from equipment user departments usually serve as the MTAC's designated technical coordinator for a specific task force. Once the committee accepts a request from an individual user, it identifies other users that may have an interest in that equipment or system and authorizes the technical coordinator to assemble a task force consisting of users identified by the MTAC. This task force then serves as an ad hoc group responsible for the establishment of a performance criteria that will be used during this particular assessment. The task force is also responsible for answering the questions of effectiveness, safety, and cost-effectiveness related to their particular assessment. During any specific period, there may be multiple task forces, each focusing on a specific equipment investigation.

The task force technical coordinator cooperates with the material management department in conducting a market survey, in obtaining the specified equipment for evaluation purposes, and in scheduling vendor-provided inservice training. The coordinator also confers with clinical staff to determine if they have had clinical experience with the equipment and the maturity level of the equipment under assessment. After establishment of a task force, the MTAC's technical coordinator is responsible for analyzing the clinical experiences associated with the utilization of this equipment, for setting evaluation objectives, and for devising appropriate technical tests, in accordance with recommendations from the task force. Only equipment that successfully passes the technical tests will proceed to a clinical trial. During the clinical trials, a task force-appointed clinical coordinator collects and reports a summary of experiences gained.

The technical coordinator then combines the results from both the technical tests and the clinical trials into a summary report for MTAC review and approval. In this role, the clinical engineer/technical coordinator serves as a multidisciplinary professional, bridging the clinical and

Figure 3.3 – Request for Review form.

Request For Review by the
MEDICAL TECHNOLOGY ADVISORY COMMITTEE

(Complete all pertinent information)

☐New product ☐New equipment ☐Replacement item ☐Single user ☐Other
Submitted by _____ To _____ Date _____
Your position (title) _____ Department name & number _____
Brief description of the item (manufacturer & catalog no.) _____
Item used for _____
Item unit cost _____ Anticipated annual usage _____
Current item being replaced (if applicable) _____
What is the annual utilization of the item being used? _____
Unit cost of the item currently being used (if not stock) _____
Manufacturer & catalog no. _____
Please give your assessment of the proposed item over the current item:
☐Better patient Care Explain: _____
☐Cost savings Explain: _____
☐Better quality Explain: _____
☐Easier to use Explain: _____
☐Other Explain: _____
Who will be the main user of this item? _____
What other facilities are using this item? (if any) _____
List current user of this item (if any) _____
Any other pertinent information (attach items/literature)

Authorized signature _____ Date _____

FOR MEDICAL TECHNOLOGY ADVISORY COMMITTEE USE ONLY

Request received by _____ Date _____
Does this item comply with standards regulations? (if applicable) _____
Additional action taken: _____
Presented to Product Standards Committee on: _____
Was not presented to the Product Standards Committee due to: _____
Action taken: _____

From: Chairman of the Product Standards Committee To: _____

Please accept our appreciation for your recommendation. The item you suggested was:

☐ Considered and approved for evaluation ☐ Considered and not approved
☐ Referred for further evaluation ☐ Pending consideration due to lack of information
☐ Other: _____

Figure 3.4 – Capital Asset Request form.

CAPITAL ASSET REQUEST

This form is required for all fixed asset purchases with a cost of $500 or more.
Please type and complete all requested information.

I. ORIGINATOR

Date | Department | Cost Center | Requested By | Extension

(Includes model #, mfg., name, accessories, color, size, style, etc.; attach any brochures, pamphlets, spec. sheets, etc.)

Item description

Estimated unit cost $ | Quantity | Total cost $ | Date required

Is item in the approved capital budget? Yes No If yes, what is the budget number?

Suggested Vendor(s)

Are building modifications needed? If yes, have you contacted facilities management?

Is installation required?

Will there be a maintenance contract? If yes, have you contacted Biomed?
Inhouse
Vendor Estimated annual cost?

Comments

Signature of department manager Date

II. Purchasing

Quotes obtained from:
Vendor #1 _____ Terms _____ F.O.B. _____
Recommended _____ Contact _____ Delivery _____
_____ Phone _____ Total price $ _____
C.O.S. Status _____

Quotes obtained from:
Vendor #2 _____ Terms _____ F.O.B. _____
Recommended _____ Contact _____ Delivery _____
_____ Phone _____ Total price $ _____
C.O.S. Status _____

Quotes obtained from:
Vendor #3 _____ Terms _____ F.O.B. _____
Recommended _____ Contact _____ Delivery _____
_____ Phone _____ Total price $ _____
C.O.S. Status _____

Signature of department manager Date

III. General Instructions

Routing	Initial	Date Rec'd	Initial	Date Fwd
1. Facilities(furniture only)				
2. HIS(computer only)				
3. Biomed(all items except furniture)				
4. Purchasing				
5. Originating department				
6. Accounting				

Step 1: Department completes Section 1
Step 2: Furniture only forward to Facilities
Step 3: Computers only forward to HIS
Step 4: All items excluding furniture forward to Biomed
Step 5: Forward to purchasing
Step 6: Purchasing complete Section 2
Step 7: Return to department
Step 8: Forward requisition to Accounting
Step 9: Secure proper approvals
Step 10: Forward requisition to Purchasing

technical needs of the hospital. To complete the process, financial staff representatives review the protocol.

The technology assessment process at this example hospital (see Figure 3.2) begins with a department or individual filling out two forms: (1) a Request for Review (RR) form (Figure 3.3) and (2) a Capital Asset Request (CAR) form (Figure 3.4). These forms are submitted to the hospital's Product Standards Committee, which determines if an assessment process is to be initiated, and the priority for its completion. It also determines if a previously established standard for this equipment exists (if the hospital is already utilizing such a technology)—if so, an assessment is not needed.

On the RR, the originator delineates the rationale for acquiring the medical device. For example, the originator must indicate how the item will improve quality of patient care, who will be its primary user, and how it will improve ease-of-use. On the CAR, the originator describes the item, estimates its cost, and provides purchase justification. The CAR is then routed to the capital budget office for review. During this process, the optimal financing method for acquisition is determined. If funding is secured, the CAR is routed to the material management department where, together with the RR, it will be processed.

The rationale for having the RR accompany the CAR is to ensure that financial information is included as part of the assessment process. The CAR is the tool by which the purchasing department initiates a market survey and later sends product requests for bid. Any request for evaluation that is received without a CAR, or any CAR involving medical equipment that is received without a request for evaluation, is returned to the originator without action. Both forms are then sent to the clinical engineering department, where a designated technical coordinator analyzes the requested technology maturity level and results of clinical experience with its use, reviews trends, and prioritizes various manufacturers' presentations for MTAC committee review.

Both forms must be sent to the MTAC if the item requested is not currently used by the hospital, or if it does not conform to previously adopted hospital standards. The MTAC has the authority to recommend either acceptance or rejection of any request for review, based on a consensus of its members. A task force consisting of potential equipment users will determine "must have" equipment functions, review the impact of the various equipment configurations, and plan technical and clinical evaluations.

If the request is approved by the MTAC, the requested technology or equipment will be evaluated using technical and performance standards. Upon completion of the review, a recommendation is returned to the hospital's Products Standard Committee, which reviews the results of the technology assessment, determines whether the particular product is suitable as a hospital standard, and decides if it should be purchased. If approved, the request to purchase will be reviewed by the Capital Budget Committee (CBC) to determine if the required expenditure meets with available financial resources, and if or when it may be feasible to make the purchase. To ensure coordination of the technology assessment program, the chairman of the MTAC also serves as a permanent member of the hospital's CBC. In this way, there is a planned integration between technology assessment and budget decisions.

The above example shows how one hospital performs technology assessment in "real-time." Section 2.2.4 discusses how another hospital ties the output of its MTAC to the capital budgeting process conducted once a year as part of 2 to 5-year capital equipment planning. In both cases, there are regular and ongoing assessment activities necessary to keep up with the frequent technology changes that may impact how patient care is best delivered.

3.3 *Technology Assessment and Clinical Engineering*

The clinical engineering program is at the threshold of a revolution in the management of healthcare technology. Increasing pressures for greater attention to quality, fiscal containment, and risk control must be matched with skillful projection of emerging healthcare technology. A well-organized program of technology assessment will have a significant impact on the hospital's bottom line, a highly desirable outcome in today's financial climate. Hospitals that operate with an organized technology planning and management program, including technology assessment, are already benefiting from the involvement of their clinical engineering professionals. The role of clinical engineers and other healthcare technology managers is threaded throughout the program. Clinical engineers and other technology managers are qualified to participate in every phase of the equipment life-cycle, from its introduction into clinical investigation to its final retirement. They match these skills with their knowledge of their hospital's technology deployment phases

ranging from capital budget planning, equipment evaluation, and performance validation, to user training, inventory control, repair and maintenance services, and incident investigation. Their involvement improves planning for new equipment and the management of the existing equipment inventory, thus impacting quality of care, financial management or cost–effectiveness, and risk management.

3.4 *Summary*

Technology assessment activities, which are centered around the MTAC, provide a comprehensive and integrated approach to analysis implementation and management of new or additional medical technologies. These activities can turn a fragmented and unpredictable decision-making process into a well-conceived approach that supports the hospital's mission. To that end, we recommend that the technology manager:

- Prepare a report for hospital administration that identifies the hospital's experiences/problems in technology planning and management. Identify the underlying causes of the problems and show how ongoing technology assessment and equipment evaluation can reduce or eliminate these problems.
- Recommend the adoption of a technology assessment process that includes identification of technology opportunities. To help start this process, you may want to adapt the use of the RR and CAR forms provided in this section.
- For identified emerging technologies of interest to your hospital, set short-term (1-year) and long-term (2 to 5-year) goals for further analysis and later implementation. Consider attending conferences and obtaining information to assist you in projecting facility preparation costs and the expected training requirements for initial clinical user assimilation for this equipment. What will be the related ongoing continuing education requirements for clinical users? For support services?

4.0 EQUIPMENT ASSETS MANAGEMENT

An accountable, systematic approach will ensure that cost-effective, efficacious, safe, and appropriate equipment is available to meet the demands of quality patient care. Such an approach requires that existing

medical equipment resources be managed and that the resulting management strategies have measurable outputs that are monitored and evaluated. Technology managers/clinical engineers are well positioned to organize and lead this function. It is assumed that cost accounting is managed and monitored by the healthcare organization's financial group.

This section describes traditional assets management strategies for medical equipment (initially called "equipment management" and "technology management" by ECRI)[23] and presents a case study of how the strategies were utilized in managing medical imaging equipment.

Monitoring output of the assets management process can provide information that fills certain gaps in data-based reports that are critical to effective hospital administrative operations and performance. For example, assets management information can assist in the preparation of the following hospital reports: (1) monthly profit and loss, (2) employee productivity, (3) cost accounting, (4) departmental utilization, (5) effect of physician practice patterns on resources, (6) use of hospital resources in relation to patient outcome, (7) analysis of charges, (8) comparative data from other hospitals, (9) profitability forecasts, and (10) clinical procedures pricing.

4.1 *Equipment Management Process*

What are the attributes of a traditional equipment management process? Clinical engineers/technology managers and their departments will be involved in the following ways:[23]

- Acquisition
  - Involvement in the process of determining the need for equipment—both short and long-term needs.
  - Prepare bid specifications and support negotiations during acquisitions.
  - Resolve all facility planning issues.
  - Careful and detailed prepurchase evaluation and selection.
  - Develop and perform acceptance testing.
- Technical Support
  - Establish a complete equipment inventory—with control records, files containing operating and service manuals, and testing and quality assurance indicators.

- Incoming equipment acceptance testing and application of control number tagging, incident investigation and handling system along with a medical device reporting system.
- Supervise corrective as well as preventive maintenance of all equipment—performed either by hospital personnel or outside vendors.
- Equipment repair—including management and integration of outside service vendor activities. It is important to focus all service-related communication between hospital departments and the clinical engineering department and between the clinical engineering department and the vendor.
- Day-to-day assistance to equipment users, promoting improvement in clinical use of equipment (e.g., periodic "equipment rounds" in the diagnostic imaging department).

■ Information and Training
- Disseminate user's manuals and other information.
- Process and track hazard, recall, and regulatory data.
- Initial and ongoing training on at least an annual basis of all clinical personnel in the safe and effective use of patient care equipment.
- Investigate equipment–related incidents, hazards, and problems. Discovered errors should be incorporated into staff training.

■ Monitoring and Evaluation
- Develop, implement, and participate in quality assurance and risk management activities.
- Periodically assess equipment management program's effectiveness with combination of objective and subjective data.
- Develop effective communication and feedback between relevant personnel in the hospital (e.g., clinical staff, purchasing, clinical engineering, hospital administration, and equipment vendors).

■ Documentation
- Activities described above must be documented to meet regulatory, accreditation, problem-solving requirements and to minimize liability.

■ Disposition
- Recommendations for and assistance in disposition of equipment by replacement, refurbishment, upgrading, or declared obsolescence.

4.2 *Technology Management Activities*

A clinical engineering department, through outstanding performance in traditional equipment management, will win their hospital's support and will be asked to be involved in the full range of technology management activities, as described below:[23]

- An equipment control program that encompasses routine performance testing, inspection, corrective and preventive maintenance, on-demand repair services, incident investigations, and actions on recalls and hazards.
- Multidisciplinary involvement in equipment acquisition and replacement decisions, development of new services, and planning of new construction and major renovations.
- Training programs for all users of patient-care equipment.
- Quality improvement (QI) as it relates to technology use.
- Technology-related risk management.

4.3 *Case Study: A Focus on Medical Imaging*

4.3.1 Equipment Management Program Development

In the mid-1980s, a large private multihospital system contemplated the start-up of a corporate clinical engineering program. It recognized that the program's involvement in diagnostic imaging equipment service would be key to the economic success of the program. They further recognized that maintenance cost reductions would have to be balanced with achieving equal or increased quality of care in the utilization of that equipment.

Program start-up took place the summer of 1987 in three hospitals that were geographically close. Within the first year, clinical engineering operations began in 11 hospitals in three regions over a two-state area. By the fall of 1990, the program included seven regions and 21 hospitals in a five-state area. The regions were organized, typically, into teams including a regional manager and 10 service providers, serving three to four hospitals whose average size was 225 beds. Although the staffs were stationed at the hospitals, some specialists traveled between different sites in the region to provide equipment service. Service providers included individuals specializing in the areas of diagnostic imaging

[x–ray and computerized tomography (CT)], clinical laboratory, general biomedical instrumentation, and respiratory therapy.

4.3.2 Financial Results/Equipment Mix

At the end of the first 18 months, the program documented over $1 million in savings for the initial 11 hospitals, a 23% reduction from the previous annual service costs. Over 63% of these savings was attributable to in-house servicing of x-ray and CT scanner equipment. The mix of equipment maintained by 11 imaging service providers— from a total staff of 30—included approximately 75% of the radiology systems of any kind found in the hospitals and five models of CT scanners from three different manufacturers.

At the end of 3 years, program-wide savings had exceeded 30% of previous costs for participating hospitals. Within the imaging areas of the hospitals, savings approached and sometimes exceeded 50% of initial service costs. The 30 imaging service providers—out of a total staff of 62—had increased their coverage of radiology equipment to over 95%, had increased involvement with CT to include nine models from five different manufacturers, and had begun in-house work in other key imaging modalities.

Tracking the financial performance of the initial 11 hospitals over the first 3 years of the program yields the following composite example:

A hospital of 225 beds was found to have equipment service costs of $540,000 prior to program start-up. Sixty-three percent of these initial costs (or $340,000) was for maintenance of the hospital's x-ray and CT scanner systems. Three years later, annual service costs for this equipment were cut in half, to approximately $170,000. That represents a 31% reduction in hospital-wide costs due to imaging service alone.

4.3.3 Discussion of Results

This corporate clinical engineering operation is, in effect, a large in–house program, serving many hospitals which all have common ownership. The multihospital corporation has significant purchasing power in the medical device marketplace and provides central oversight of the larger capital expenditures for its hospitals. The combination of the parent organization's leverage and the program's commitment to serve only hospitals in the corporation facilitated the development of positive relationships with medical device manufacturers. Most of the manufac-

turers did not see the program as competition, but rather as a potentially helpful ally in the future marketing and sales of their equipment and systems.

4.3.4 Program Staff and Resources

What staff provided these results? All service providers were trained in either the medical imaging industry or the military. All were experienced at troubleshooting electronic subsystems to component level. Typically, these individuals had prior experience on the manufacturers' models of equipment under their responsibility. Most regional managers had prior industry, third-party, or in-house imaging service management experience. Each service provider had the test equipment necessary for day-to-day duties. Each individual could expect at least 2 weeks of annual service training to keep appropriate skills current. Desired service training could be acquired in a timely manner from manufacturers and/or third-party organizations. Spare or replacement parts inventory was minimal, because of a philosophy of component-level repair whenever possible and practical, and because of the program's ability to get parts from manufacturers and other sources either locally or shipped in overnight.

4.3.5 Quality Indicators

The program measured the following quality indicators on an annual basis:

- User satisfaction, e.g., "are the administrative, clinical department head and medical staff expectations for imaging service being met?" This was measured by survey and also by noting the level at which most communication, technical, and/or management problems were resolved.
- Equipment downtime—the number of times a clinical procedure, examination, or intervention was canceled or had to be rescheduled due to inoperative equipment.
- Documentation of technical staff service training (to include records of an individual's training activities with training subject, format, length, date, location, and certification obtained).
- Types of user equipment errors and their effect on patient outcomes.

- Regular attention to hospital technology problems (by involvement in hospital safety committees).

User satisfaction surveys indicated a high degree of confidence in program service providers by imaging department managers. Problems relating to technical, management, communication, and financial issues did occur regularly, but the regional manager ensured they were resolved in a timely manner. Faster response to daily imaging equipment problems, typically by on-site service providers coupled with regular preventive maintenance (PM) according to established procedures, led to reduced equipment downtime. PM and repair service histories were captured in a computer documentation system that also tracked service times, costs, and user errors and their effects. Assisting the safety committee became easier with the ability to draw a wide variety of information quickly from the program's documentation system.

4.3.6 From Equipment Management to Technology Management

Early success in imaging equipment management led to the opportunity to do some additional value-added projects, such as:

- Moving and reinstallation of x-ray rooms; this preserved existing assets and opened up valuable space for installation of newer equipment.
- Upgrades of CT scanner systems—e.g., addition of an off-line computer terminal which increased patient throughput and, therefore, increased hospital revenues (by allowing the previous patient's information to be studied while new patients were being scanned).

These value-added cost-effective projects, in turn, caused the parent organization to involve the corporate clinical engineering program in more imaging technology management activities. This meant assisting corporate and hospital staff with:

- Making diagnostic imaging equipment acquisition decisions—particularly helpful in an era of extremely tight capital budget limitations.
- Considering the standardization of imaging systems, thus allowing for decreased training and support costs.

- Improving the quality and cost-effectiveness of key imaging consumables purchasing (e.g., buying imaging glassware at substantial discounts from a distributor over which strong quality control pressures could be exercised).
- Making better equipment replacement decisions by reviewing the system's repair history and the input from the in-house service provider (who helped the equipment users compare the system's capabilities to those of current state-of-the-art equipment).
- Developing computer documentation systems that could assist in early identification of risk-related trends in specific types of equipment or groups of equipment users so that appropriate corrective action could be taken.
- Increasing involvement in the facilities planning issues for the imaging equipment being purchased, thus avoiding costly mistakes.
- Improving technology planning based on utilization and up-time indicators.

The parent organization came to realize that these technology management activities could potentially have a greater financial and quality impact on their hospitals' healthcare delivery than equipment management. In the example of one CT upgrade (which was completed over 2 weekends with no down-time) there was a positive financial impact in excess of $600,000, and improved quality of care by allowing faster off-line diagnosis of patient scans. But opportunity for this kind of contribution would never have occurred without the strong base of a successful equipment management program staffed with qualified individuals who receive ongoing training.

4.4 *Summary*

The case study in this section demonstrates how equipment assets can be comprehensively managed by clinical engineering personnel.

To implement and optimize an equipment assets management program:

- Consider a full range of strategies for equipment technical support. Plans may include use of a combination of equipment service providers such as manufacturers, third-party service groups, shared services, and hospital-based (in-house) engineers and biomedical equipment technicians (BMETs). Seek to have all of these service pro-

viders under the general responsibility of the technology manager to ensure optimal equipment performance through comprehensive and ongoing best-value equipment service.

- After obtaining a complete hospital medical equipment inventory (noting both original manufacturer and typical service provider), conduct a thorough analysis of hospital accounts payable records for at least the past 2 years, compiling all service reports and preventive maintenance-related costs from all possible sources. Document in-house and external provider equipment service costs, extent of maintenance coverage for each inventory time, equipment-user operating schedule, quality of maintenance for each item, appropriateness of the service provider, and reasonable maintenance costs.
- Establish an effective equipment technical support process. With an accurate inventory and best-value service providers identified, negotiate service agreements/contracts with external providers using prepared terms and conditions. Develop a log-in system for the external providers.
- Have in-house clinical engineering staff ensure ongoing external provider cost-control utilizing the following tools:
  - Service purchase orders (POs)—in-house staff will ask the right technical questions, establish friendly relationships, determine if equipment is worth repairing and obtain exchange prices for parts.
  - Service reports—review them for accuracy and proper use of log-in system.
  - Invoices—match invoice with service report to verify opportunities.
  - Review service histories—look for symptoms such as need for user training, repeated problems, run-on calls billed months apart, or evidence of defective or worn-out equipment.
- Manage emergency equipment rentals.
- Develop, implement, and monitor service performance criteria (i.e., response time, uptime, quality of service, reports, etc.).

To optimize technology management programs:

- Be willing to assume additional responsibilities for technology planning and management in all related areas.

- Develop policies and procedures for your hospital's technology planning and management program.
- With life-cycle costs determined for key high-risk or high-cost devices (Section 2) evaluate methods to provide additional cost savings in equipment operation and maintenance.
- Be involved with networking systems within the hospital. As computer technology applications increase, the requirements to review technology-related information in a number of hospital locations will increase.
- Determine what environmental conditions and facility changes are required to accommodate new technologies or changes in standards and guidelines.
- From documentation of equipment performance and maintenance costs, as well as knowledge of current clinical practices, assist other hospital personnel in determining the best time and process for planning equipment replacement.

5.0 EQUIPMENT ACQUISITION AND DEPLOYMENT

Medical technology planning and management objectives for improved performance at reduced cost should be clearly indicated throughout the equipment acquisition and deployment phases. This section first details the existing processes and then a number of strategies that have been demonstrated to help meet these objectives.

5.1 *Process of Acquiring Technology*

5.1.1 Overall Process

Typically, medical device systems will emerge from strategic technology planning and technology assessment processes as "required and budgeted" needs. At acquisition time, the following process should be followed:

1. A needs analysis should be conducted, reaffirming clinical needs and device-intended applications; the Request for Review (RR) documentation (Figure 3.3) from the assessment process or Capital Budget Request (Figure 2.2) and Incremental Financial Analysis

(Figure 2.3) from the planning process may provide appropriate justification information; a Capital Asset Request (CAR) should be completed (Figure 3.4).
2. Materials management and clinical engineering personnel should ensure that this item is a candidate for centralized and coordinated acquisition of similar equipment with other hospital departments.
3. Written prepurchase evaluation guidelines should be followed (see below).
4. Purchasing takes place, wherein final equipment negotiations are conducted and purchase documents are prepared and a purchase order is made.

5.1.2 Prepurchase Evaluations

Typical hospital prepurchase evaluations include the following steps as a minimum (the level of information for each step depends on the acquisition); see Section 5.2 for further details:

1. Analysis of needs and development of a specification list.
2. Developing a vendor list and requesting proposals.
3. Analyzing proposals, site planning.
4. Evaluating samples.
5. Selecting finalists.
6. Making the award.
7. Delivery and installation.
8. Acceptance testing.

Formal request for proposals (RFPs) from potential equipment vendors are required for intended acquisitions whose initial or life-cycle cost exceeds a certain threshold, e.g., $100,000.

5.2 *Acquisition Process Strategies*

5.2.1 Cost of Ownership

The cost of ownership concept can be utilized when considering what factors to include in cost comparisons of competing medical devices. Cost of ownership encompasses all direct and indirect expenses associated with medical equipment over its lifetime.[25] It expresses the cost

factors of medical equipment for both the initial price of the equipment (which typically includes the equipment, its installation, and initial training cost) and support over the long-term. Long-term costs include ongoing training, equipment service, supplies, connectivity, upgrades, and other costs. Healthcare organizations are just beginning to account for the full range of cost of ownership factors in their technology assessment and acquisition processes, such as: acquisition costs, operation and maintenance costs (installation, supplies, downtime, training, spare parts, test equipment and tools, and depreciation). It is estimated that the purchase price represents only 20% of the life-cycle cost of ownership.

5.2.2 Utilization Information

When conducting needs analysis (Step 1. in Section 5.1.2 above), actual utilization information from the organization's existing same or similar devices can be very helpful. One leading private multihospital system has implemented the following approach to measuring and developing relevant management feedback concerning equipment utilization. It is conducting equipment utilization review for replacement planning, for ongoing accountability of equipment use, and to provide input before more equipment is purchased.

This private system attempts to match product to its intended function and to measure daily (if necessary) the equipment's actual utilization. Utilization assumptions are made for each hospital and its clinical procedural mix. Equipment functional requirements to meet the demands of clinical procedures are taken into account. The following is a simplified description of how this utilization information model is developed.

For imaging procedures: knowing devices needed and minutes needed (annually) to accomplish certain procedures, and based on the hospital's past case mix, the central staff can determine equipment needs matched to new/replacement functional capacities. Analysis includes the following information:

- From the equipment inventory, equipment installation dates and condition codes [1 (new) to 5 (scrap), as determined by technical service appraisal and service expenses].
- From the procedure mix, like procedures are grouped by modality.

- Procedure/equipment volumes information is retrieved from the central billing system.
- Operational constraints are determined (the total period of time equipment is available during the day). For example, comparing a Radiographic and Fluoroscopic (R and F) x-ray room's ideal utilization versus a straight radiographic (Rad) room's ideal utilization is identified in Table 5.1.

Table 5.1 – R and F Room vs. Rad Utilization

Exams	(hrs/day)	Days per year	Annual minutes available
Fluoro – am only	4 x (60 min/hr)	260	62,400
Rad – pm only	6 x (60 min/hr)	260	93,600
Rad room – full day	10 x (60 min/hr)	260	156,000

Functional needs are then matched to certain equipment (e.g., for myelograms, a certain x-ray table and other specific accessories may be required).

5.2.3 Life-Cycle Cost Analysis

Life-cycle cost analysis is a tool used during technology planning, assessment or acquisition "either to compare high-cost, alternative means for providing a service, or to determine whether a single project or technology has a positive or negative economic value. The strength of life-cycle cost analysis is that it examines the cash flow impact of an alternative over its entire life, instead of focusing solely on initial capital investments."[25]

"Life-cycle cost analysis facilitates comparisons between projects or technologies with large initial cash outlays and those with level outlays and inflows over time. It is most applicable to complex, high-cost choices among alternative technologies, new services, and different means for providing a given service. Life-cycle cost analysis is particularly useful for decisions that are too complex and ambiguous for experience and subjective judgment alone. It also helps decision-makers perceive and

include costs that often are hidden or ignored, and that may otherwise invalidate results."[25]

"Perhaps the most powerful life-cycle cost technique is Net Present Value (NPV) analysis, which explicitly accounts for inflation and foregone investment opportunities by expressing future cash flows in present dollars."[25]

Examples where life-cycle cost and NPV analysis prove very helpful are in deciding whether to replace/rebuild or buy/lease medical imaging equipment. The kinds of costs captured in life-cycle cost analysis include the following: decision-making costs, planning agency/Certificate of Need costs (if applicable), financing, initial capital investment costs including facility changes, life-cycle maintenance and repairs costs, personnel costs, and other (reimbursement consequences, resale, etc). See Table 5.2.

Table 5.2 – Example of a Life-Cycle Cost Analysis and Net Present Value

	Initial Capital	Year 1	Year 2	Year 3	Year 4	Year 5
1. Hardware costs	$225,000	$0	$0	$0	$0	$0
s/w license	$17,500	0	$18,200	$18,928	$19,685	$20,473
2. Facility costs	$25,000	0	0	0	0	0
3. Disposable costs	0	$4,500	$4,680	$4,867	$5,062	$5,264
4. Support costs	0	$3,375	$3,510	$3,650	$3,796	$3,948
5. Service costs	0	0	$11,250	$11,700	$12,168	$12,654
6. Training costs	0	0	$1,125	$1,170	$1,217	$1,265
7. Misc. costs	0	$1,125	$1,170	$1,217	$1,265	$1,316
Cash outflow	$267,500	$9,000	$39,935	$41,532	$43,193	$44,920
8. Present value of $1, discounted at 10%	N/A	.9091	.8284	.7513	.6830	.6209
Formula $Pv = 1/(1+i)^n$						
9. Net present values	$267,500	$8,182	$33,082	$32,203	$29,501	$27,891
Total present value	$398,359					

5.2.4 Equipment Evaluation

One of the best strategies to ensure that a desired technology is truly of value is to conduct a careful analysis in preparation for its assimilation into hospital operations. The process of equipment prepurchase evaluation provides information that can be used to screen unacceptable performance by either the vendor or the equipment before it becomes a hospital problem.

The prepurchase evaluation process consists of technical, clinical, financial, and operational aspects. These aspects were evaluated earlier as described in the technology assessment function; however, the emphasis here is on clinical engineer/technology manager responsibilities. It is assumed that in order to fulfill these duties, this individual is familiar with emerging and evolving technologies so they can translate the clinical needs of users into an effective and comprehensive bid specification document. The document should be clear to facilitate a competitive bidding environment and a valid comparison of vendors and their products. This is an important document that sets the whole equipment evaluation and selection process into motion. Validation criteria for key elements such as system configuration, extent of facility preparation and operational disturbance, equipment performance requirements, user and service provider training, warranty, documentation, delivery schedule, and implementation plan should be addressed. Cost of service support and price for future upgrades should be locked in.

Once the vendor has responded to informal requests or formal RFPs, the clinical engineering department should be responsible for evaluating the technical responses, while the materials management department should evaluate the financial responses.

In translating clinical needs into a specification list, key features or must-have attributes of the desired device are identified. In practice, clinical engineering and materials management should develop a must-have list and a list of extras. The extras list includes features that may tip the decision in favor of one vendor, all other factors being even. These specification lists are sent to the vendor and are effective in a self-elimination process that results in saving time for the hospital. Once the must have attributes have been satisfied, the remaining candidate devices are evaluated technically and the extras are considered. This is accomplished by assigning a weighting factor (e.g., 0 to 5) to denote the relative importance of each desired attribute. The relative ability of each device

to meet the defined requirements are then rated. Consider the following examples of attributes:

- Accuracy and repeatability.
- Ease-of-use.
- Reliability.
- Expected user's skill level.
- Serviceability and warranty.
- Performance.
- Compatibility and interchangeability.
- Upgradability or expandability.
- Safety.
- Cost-effectiveness.

Each of these attributes is important, but some are more important than others. In assigning the weighting factors, the clinical engineer or technology manager must take into account the relative importance of each of these attributes. Clinical engineering should create a highly competitive purchasing environment that enables a direct comparison of vendors. Therefore, the RFP should provide details of delivery, training and installation, as well as a detailed description of the must have and the extras, the cost of service and upgrades, and should identify a recourse for vendor deficiencies.

5.2.5 The Conditions of Sale Document

One strategy that strengthens the acquisition process is the Conditions of Sale document, (Figure 5.1). This multifaceted document integrates equipment specifications, performance, installation requirements, and follow-up services. The Conditions of Sale ensures that negotiations are completed before a purchase order is delivered and each participant is in agreement about the product to be delivered. As a document of compliance, the Conditions of Sale specifies the codes and standards having jurisdiction over that equipment. This may include provisions for future modification of the equipment, compliance with standards under development (e.g., the Medical Information Bus), compliance with National codes, and provision for software upgrades.

Figure 5.1 – Conditions of Sale document.

CONDITIONS OF SALE

BIOMEDICAL ENGINEERING

ITEM | CONDITION OF SALE NO. | DATE

VENDOR | MANUFACTURER

PART I RADIOLOGY EQUIPMENT

In accepting this purchase order. The manufacturer or licensed representative shall assume the responsibility of complying with the Regulations for the Administration and Enforcement of Radiation Control for Health and Safety Act of 1968. In the event of noncompatibility the manufacturer or licensed representative shall petition for a variance to the FDA Center for Devices and Radiological Health and make available to this institution a copy of this variance whether the variance is accepted or not.

PART II-GENERAL PATIENT-RELATED DIAGNOSTIC AND THERAPEUTIC ELECTRICAL EQUIPMENT

The electrical equipment in this purchase order must meet the standards set forth by the Biomedical Instrumentation Department. No payment shall be made to the manufacturer or licensed representative unless the following standards are met:

Applicable	Non Applicable	See Comments	
			1. Equipment shall pass the appropriate electrical leakage current tests at 115 volts 60 cycle power in the grounded, and ungrounded correct and reverse polarities. All measurements are referenced to ground:
			a. Patient contact equipment-50 ua from leads and 100 ua from chassis.
			b. Patient contact equipment isolated patient connection-10 ua from the leads and 100 ua from the chassis.
			c. Nonpatient equipment-500 ua from the chassis
			d. Battery-operated equipment.
			2. Equipment will be supplied with a 3-wire power cord and hospital grade plug.
			3. Equipment shall pass an initial utilizing the manufacturer's performance insurance procedures. All tests will be performed at this Institution by the manufacturer or licensed representative or the Biomedical Instrumentation Department. Test results documentation will be held with the Biomedical Instrumentation Department.
			4. Upon being placed in operation in service training as determined by the hospital will be provided to the hospital staff free of charge by the manufacturer or licensed representative prior to the expiration of the warranty period.
			5. Two complete sets of operating instructions schematics and maintenance manuals for each separate identifiable item of equipment shall be provided.
			6. The manufacturer will guarantee the direct sale to this institution of test fixtures and spare parts that are needed to maintain the equipment in proper condition during its life expectancy. Copies of all customer service bulletins that affect the operation of any equipment purchased under this sale must be provided institution for as long as the equipment is manufactured. Parts, fixtures, etc., that are part of the above modification will be made available for sale to this institution for installation into the equipment purchased under this order.
			7. Compliance with all applicable local and national codes and standards is required, including the standards of organization such as NFPA, JCAHO, AAMI, EPA, ANSI, and UL.
			8. The vendor warrants that the equipment shall be free from defects under normal use and service for a period of____months after the date of installation.

COMMENTS

CONDITIONS OF SALE ISSUED BY: | DIRECTOR BIOMEDICAL ENG. DEPT. | DATE

CONDITIONS OF SALE ACCEPTED BY: | MANUFACTURER'S REPRESENTATIVE | DATE

CONDITIONS OF SALE MET-APPROVED FOR PAYMENT

ISSUED BY: | DIRECTOR BIOMEDICAL ENG. DEPT. | DATE

Clinical engineering departments may use the Conditions of Sale as a tracking document to ensure that all conditions of purchase are met, from delivery through clinical implementation.

As a document of responsibility, it discloses the full cost of ownership, which is not always apparent from specification sheets and vendor demonstrations. This is especially important to administrative personnel with capital budget approval responsibility and to managers with operating budget responsibility.

When the Conditions of Sale has served as a condition for payment, vendor cooperation and response have been satisfactory. However, this condition is effective only when there is appropriate communication among the equipment users, materials management, accounts payable, clinical engineering, and the vendor to prevent unnecessary delays in payment. Experience has shown that without a highly structured acquisition-to-payment procedure, the vendor-client relationship degrades and client satisfaction becomes more costly.

Discretion can be exercised as to when it is appropriate to incorporate a Conditions of Sale with a purchase order. The purpose of the Conditions of Sale is to protect the hospital and to extend as many operational options as possible. The protection is accomplished by requiring vendors to provide only safe equipment (the first part of the document), by demanding compliance with the ever-growing number of federal and other regulatory/accrediting agencies, by reviewing documented test results, by conditioning the successful conclusion of a purchase transaction on the performance of incoming acceptance test, by including user training as a vendor requirement, and by delineating vendor responsibility over the warranty period.

During the equipment life-cycle, the hospital can achieve a higher level of operational efficiency when in-house personnel are adequately trained in the operation and maintenance of the equipment, when the equipment is delivered with the appropriate operation and maintenance manuals, when parts are identified and obtainable, and when safety-related upgrades are provided. All these terms are included in the Conditions of Sale; therefore it is important that the vendor has sufficient time to review it. When it was first introduced at one large private hospital over 10 years ago, this document was refused by many vendors. Over time its importance to all parties became obvious and vendor compliance with its terms and conditions increased. In situations where vendors did choose to comply with the conditions, it quickly became a

win-win situation. The complying vendor creates an environment for repeated business, and the hospital is operating equipment that is known to be efficient and safe. Over time the document has been copied by other hospitals, including those in many states, as well as in Canada, Central and South America, and Europe.

In an attempt to clarify what should be covered by the Conditions of Sale, it can be simply stated that all powered equipment in patient care areas should be subjected to and demonstrate compliance with the terms and conditions of the Conditions of Sale. Powered equipment in nonpatient care areas should be subjected to and demonstrate compliance only with selected portions of the document. For example, a personal computer intended for use in a patient room will have to demonstrate a higher level of compliance than a personal computer that is planned for use in a nonpatient area. All patient care powered equipment regardless of method of purchase (capital budget or expensed through the operating budget) should have an accompanying Conditions of Sale.

In summary, all powered equipment purchases should be subjected to the terms and conditions as outlined in the Conditions of Sale. Powered equipment that is going to be used in patient care areas will have to comply with all or most of the terms, while powered equipment that is going to be used in nonpatient care areas may have to comply with only a few of the terms.

5.2.6 Making the Award

Standard purchase orders that include the Conditions of Sale for medical equipment are usually used to initiate the order. At the time the order is placed, clinical engineering is notified of the order. In addition to current facility conditions, the following conditions are addressed as a minimum:

- Installation and approval requirements, responsibilities, and timetable.
- Payment, assignment, and cancellation.
- Software requirements and updates (e.g., software availability, licensing fees).
- Documentation.
- Clinical and technical training.
- Acceptance testing (hospital/facility and vendor).
- Warranty, spare parts, and service.
- Price protection.

5.2.7 Acceptance Testing

All medical equipment must be inspected and tested before it is placed into service regardless of whether it is purchased, leased, rented, or borrowed by the hospital. Acceptance testing involves the following:

- An incoming inspection designed to verify that each medical device received is capable of performing its designed function and is electrically safe. If installation is required it should be covered as well.
- Baseline measures that may be later used to resolve specified problems.
- Compliance with the equipment assets management process.

Relevant factors in assuring compliance with the equipment assets management process include the following:

- Verification that the selected vendor has installed and delivered a complete system with all accessories and other needed supplies.
- Documentation of full compliance with terms prescribed in the Conditions of Sale (see Section 5.2.5) and agreed upon when the purchase order was awarded.
- Initiation of an assets control record by the clinical engineering department.

The last item above is the point the equipment enters the equipment maintenance program, the warranty period is initiated (if applicable), and testing criteria are established and documented. In any hospital, clinical engineering should receive immediate notification if a very large device or system is delivered directly to another department (e.g., imaging or cardiology) for installation. Clinical engineering should be required to sign off (see Conditions of Sale, Section 5.2.5) on all purchase orders for devices after installation and validation of satisfactory operation. Ideally, the warranty period on new equipment should not begin until installation and acceptance testing are completed. It is not uncommon for a hospital to lose several months of free parts and service by the manufacturer when new equipment is, for some reason, not immediately installed after delivery.

5.3 *Clinical Team Requirements*

As stated earlier, during the technology assessment and acquisition processes, clinical decision-makers analyze the following criteria concerning proposed technology acquisitions, specifically as they relate to clinical team requirements:

- Ability of staff to assimilate the technology.
- Medical staff satisfaction (short-term and long-term).
- Impact on staffing (numbers, functions).
- Projected utilization.
- Ongoing related supplies required.
- Effect on delivery of care and outcomes (convenience, safety, or standard of care).
- Result of what is written in the clinical practice guidelines.
- Credentialing of staff required.
- Clinical staff initial and ongoing training required.
- Effect on existing technology in the department or other services/departments.

5.4 *Summary*

Technology planning and management is a system that offers tools for planning and controlling medical technology performance over the equipment life-cycle. Its impact on patient care is a function of many factors. Hospitals will improve their technology-dependent services by proactively assessing the differences between proposed technologies and currently used ones, by evaluating which technologies best match their needs, and by continually performing financial review of the technologies they use. The technology planning and management program will facilitate technology-related planning, assist hospital senior management in accurately determining fiscal needs, and assist in ensuring efficient, high quality patient care services.

To implement a medical technology planning and management program, follow these guidelines:

- Participate in equipment acquisition decisions. Work with the administration and materials management department to establish the acquisition process outlined in Section 5.1.

- Support a policy of equipment standardization, where appropriate, to decrease risk, user training, and maintenance costs.
- Utilize the acquisition process strategies outlined in Section 5.2 as appropriate to the technologies being acquired:
  - Cost of ownership can be used for technologies with lower initial cost and with significant ongoing accessory costs (e.g., infusion systems) or for technologies with higher initial cost and high resource requirements over equipment lifetime (e.g., MRI).
  - Utilization information can be used for determining the ideal functions and features, and the quantity of needed equipment.
  - Life-cycle cost analysis can be used in replace/rebuild or buy/lease decisions for medical imaging equipment.
  - For many acquisitions, an evaluation process should be conducted, grading the various competing devices' ability to provide required attributes.
  - In awarding purchase orders, the conditions described in Section 5.2.5 should be addressed.
  - Acceptance testing of all acquired equipment should be conducted as described.
  - For appropriate classes of equipment as defined by your hospital, utilize an adapted version of the Conditions of Sale document to strengthen the acquisition process.
- Utilize the criteria given in Section 5.3 to assist other clinical decision-makers in analyzing clinical team requirements and related factors for proposed technology acquisitions.

6.0 RISK MANAGEMENT AND QUALITY IMPROVEMENT

Following the successful completion of the acceptance testing phase, which may be based on a number of acceptable procedures or performance, the next important task for the clinical engineer or technology manager begins— the task of managing technology throughout its expected life, by focusing on improving performance through monitoring quality assurance indicators and reduction of risk potential. The healthcare delivery system is comprised of many complex activities, each of which provides opportunities for interactions among people, agents of technology, and interventions. In each intervention, there is a

level of real risk coupled with some uncertainty. Risk measures the probability and severity of loss or injury, while uncertainty refers to a lack of knowledge or a lack of certainty.[26] While it is not simple to quantify the risk-to-benefit ratio in a particular intervention, risk management evolves into a responsibility that includes prediction of injury, avoidance of exposure to risks, and minimization of liability exposure. A proactive approach to identify and correct problems requires the use of management tools that reduce risk and increase benefit. This section describes how the manager can implement equipment-related decision-making programs that reduce uncertainty and improve quality through the implementation of a proper evaluation and monitoring system.

6.1 *Reducing Risk*

Significant progress in controlling risk has been achieved with the implementation of equipment assets management programs. With the recent development of dynamic equipment risk factors and the associated failure analysis technique, proactive techniques to contain risk can be implemented.[27] These techniques should be used for assessing new equipment as well as for managing existing inventory. The physical risk associated with the application of equipment was previously described as "the possible consequences to the patient and/or operator in the event of equipment failure or malfunction."[28] It is a criteria that categorizes risk level at the time equipment enters into the hospital's equipment inventory. The dynamic risk factor modifies this level and individually identifies each piece of equipment within an equipment category according to the accumulated experiences over the equipment life-cycle. These experiences include number of failures, extent of maintenance, number of user errors, number of recalls, hazards, or incidents, and equipment age.

Every organization has a variety of objectives, from profit and growth to the performance of a public service. However, a fundamental management commitment to minimizing the adverse effect of accidental loss to an organization is the founding principle of risk management programs. This is the process of making and carrying out decisions that minimize incidents. The program requires the development of risk criteria, the identification of problems, and an action plan to reduce them.

The medical technology planning and management program participates in the organization's effort at the beginning and throughout the

equipment life-cycle by assessing equipment performance. The impact of both risk and quality are monitored prior to the purchasing decision, during installation, maintenance and repair, and as indicators for disposition or replacement.[29] Faulty design, poor manufacturing, lack of compatibility with existing technology, and a mismatch with user skills and/or needs can be corrected during the equipment selection and acceptance testing. Incorrect operating procedure, lack of or an inadequate maintenance program, or faulty repair work can be corrected by failure analysis and corrective action based on an information collection and evaluation system that has been described in the *JCAHO Plant, Technology, and Safety Management* publication.[30]

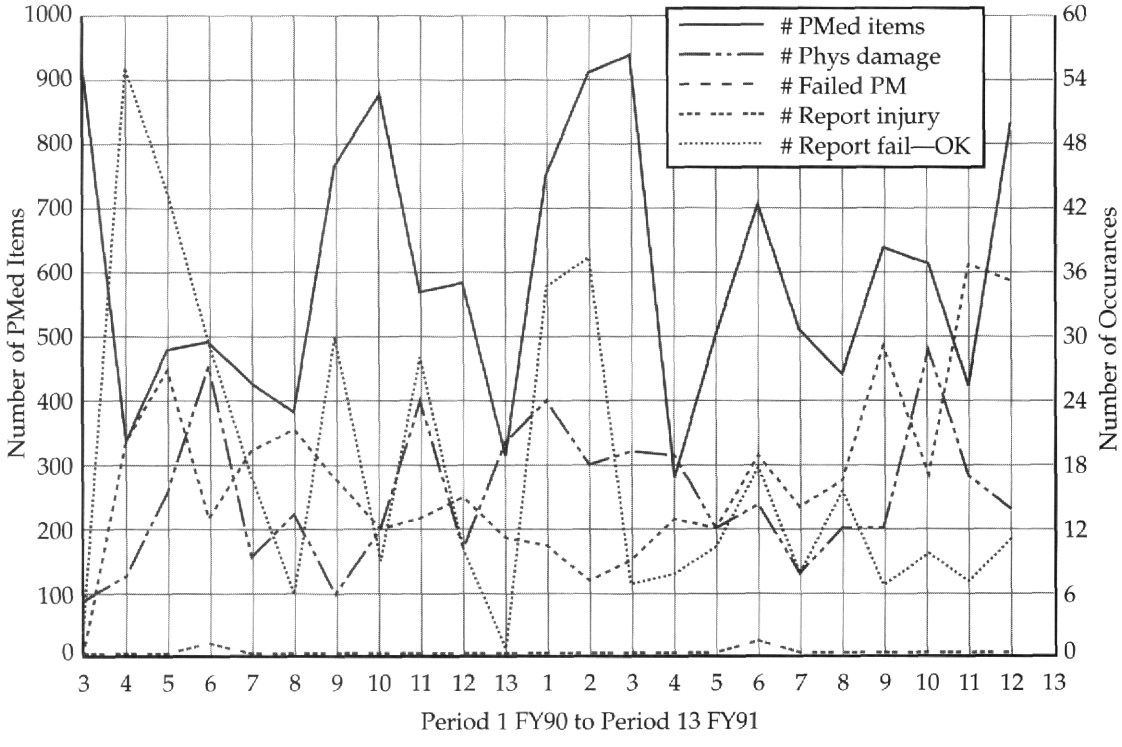
The collection of equipment failure analysis information over several years indicates that equipment risk factor is a dynamic phenomenon. The equipment-related dynamic risk factor is a modification of a static factor which is assigned to each type of equipment at the time it first enters the equipment assets management program. This static risk factor is modified continually over the equipment's life-cycle by risk factors that are derived from information collected about experiences with each equipment performance.[31]

Periodically, a summary report of significant equipment-related performance is prepared. The report's data is made up of elements that show (1) the ratio of the number of completed-to-scheduled inspections, (2) the number and percent of devices failing to pass prescribed inspection, (3) the number and percent of devices for which a user's complaint was registered (however no problem was found), (4) the number and percent of devices that show physical damage, (5) devices that were involved with an unusual event (e.g., incident), and (6) the number of devices for which a user's complaint was justified. Each element is counted as an event, and thresholds above which unsafe conditions may exist can be determined. Figure 6.1 shows a sample of trend monitoring of five equipment performance indicators in a failure elements report, based on expectation and the empirical data that was collected over a period of 2 years.

A method was previously described that evaluates the extent of service support needed for maintaining equipment in the clinical environment.[32] It is based on features such as the equipment function, the maintenance required and the associated physical risk. Once determined, the physical risk feature is a constant. However, in reality equipment-related risk is changing over its life-cycle, thus representing a dynamic factor. This allows technology managers to plan for the service

support of individual equipment continually during clinical use. The ability to monitor changes in the dynamic risk factor or management tool can guide the optimization of the equipment management program.[29]

Figure 6.1 – Failure elements report.



Each medical device has its own history and associated risk level. The failure elements report allows the structured progression from dealing with isolated device performance to clustering equipment users' behavior and their interaction with the devices. Essentially, this change is a translation of an equipment repair service into a technology planning and management function that improves hospital performance by selectively monitoring and controlling equipment-related variances. This ensures better equipment selection, the establishment of more effective user training (proportional to outcome-measured risk), more efficient scheduled maintenance, and assists in prioritizing equipment for capital replacement. Trending this information over time permits an annual review of the effectiveness of this aspect of the clinical engineering program, as well as documented opportunity for improvement.

This risk assessment and reduction program should be complemented with professional communication regarding on-going

equipment performance between clinical engineering, the user's department, and various manufacturers. It will result in the availability of better and safer products, less complex operation and maintenance instructions, more effective in-service training, and rapid resolution of equipment problems when action is needed.

6.2 *Quality Improvement*

A quality improvement (QI) process was developed by the JCAHO, in order to provide a patient care environment that is continually safer and provides higher quality patient outcomes. This is an on-going hospital-wide process that is the responsibility of the entire staff at all levels. It empowers employees to make changes that improve service outcome. It is a philosophy and a methodology focusing on continual assessment of performance and improvement of clinical, operational, administrative, and other hospital processes. One of the process methods is based on 10 steps that are the building blocks for an information collection and evaluation system—measurement and assessment of performance—that allows managers to focus, through an organized system, on improving that performance. The process is proactive and consists of (1) structure—written manual of policies and procedures defining goals and objectives, (2) process—understanding of the operation and the ability to determine opportunities for improvement, and (3) outcome base—an evaluation of the program impact as determined by function reports. Problems are considered outliers and, through appropriate selection, can be order-ranked. Selectively, the top 10% to 20% can be addressed at a time. This is a continuous structured approach that improves the quality of the technology planning and management program by setting minimum acceptable performance goals, by increasing equipment availability for intended clinical use, by ensuring optimal device function, and by eliminating device-related incidents.[33] The 10 steps are:

Step 1: Assign Responsibility

Each manager should be responsible for, and actively participate in, monitoring and evaluation. The manager assigns responsibility for the specific duties related to monitoring and evaluation. The manager ensures that all of the program's staff is participating in the process.

Step 2: Delineate Scope of Service

Each department should consider the scope of service it provides and establish a basis for identifying important aspects of service to monitor and evaluate. The scope of service is a complete inventory of what the department does. It identifies key functions.

Step 3: Identify Important Aspects of Service

Important aspects of service are those that are high risk, high volume, and/or problem prone. Staff should identify important aspects of service so monitoring and evaluation focuses on activities with the greatest impact on the quality of patient care. This leads to more specific determination of function and assignment of priorities.

Step 4: Identify Indicators

Indicators of quality should be identified for each important aspect of service. An indicator is a measurable variable related to a structure, process, or outcome of service.

Step 5: Establish Thresholds for Evaluation

A threshold for evaluation is the level or point at which intensive evaluation of service is triggered. Staff should agree on a threshold for each indicator. A threshold may be 0% or 100% or any other appropriate level. Setting a threshold at 0% or 100% means that the staff feels that even one occurrence in that area would be so serious or rare that it should trigger an intensive quality evaluation. Once a threshold is established, the team can decide, based on measured outcome, to move the threshold up or down.

Step 6: Collect and Organize Data

Appropriate staff should collect data pertaining to the indicators. Data should be organized to facilitate comparison with the thresholds for evaluation.

Step 7: Evaluate Service

When the cumulative data related to an indicator reaches the threshold for evaluation, appropriate staff members must evaluate the service provided to determine whether a problem exists. This evaluation, which may take the form of peer review, should focus on possible trends and performance patterns in addition to specific cases. The evaluation should also attempt to identify causes of any problems and methods by which service or performance may be improved.

Step 8: Take Actions to Solve Problems

When problems are identified, action plans must be developed, approved at appropriate levels, and enacted to solve the problem and take the opportunity to improve service. This step emphasizes the team approach to problem resolution.

Step 9: Assess Actions and Document Improvement

The effectiveness of any actions taken should be assessed and documented. If further actions are necessary to solve a problem, they should be taken and their effectiveness assessed. Statistical analysis assessment allows one to monitor the degree of improvement that is taking place.

Step 10: Communicate Relevant Information

Findings from and conclusions of monitoring and evaluation, including actions taken to solve problems and improve service, should be documented and reported monthly through the hospital's safety committee.

The facilitation of a QI program for medical technology should start during the performance of the technology audit described in Section 2. Equipment inventory is documented and classified into five different risk classes according to the institution's experience with that and similar devices, equipment function, industry standards, age, and current device condition. The intensity and the frequency of user/device interactions should also be included as potential monitors. The next step is to select a valid indicator that is a measure of equipment clinical availability, functionality or financial performance, or safety. A valid indicator is specific, sensitive, relevant, and reliable.[34]

The following example demonstrates the use of the QI techniques/tools as part of a technology planning and management program. To improve engineering services provided, equipment inventory is classified, services are scheduled, acceptable standards established (e.g., expected uptime and repair turnaround, material and labor costs, number and extent of incidents, etc.). The data elements of the maintenance activity are identified as follows:

1. The type and number of devices scheduled for service.
2. Total number and type of devices inspected.
3. The type and number of devices that failed an inspection.
4. The type and number of devices for which on-demand service was requested.
5. The type and number of devices found with physical damage.
6. The type and number of devices for which a user's complaint was registered, but no problem found.
7. The type and number of devices involved in an incident.
8. The type and number of devices that were serviced more than one time in any 7-day period.
9. The type and number of devices for which abnormal labor or replacement parts were required.

Once indicators are identified, data collection can begin. Temptation to apply corrective action "on the fly" should be avoided, thus permitting trending of data over time. Performance goals need to be determined and thresholds set to support them. When sufficient data is collected, indicators can be evaluated, determining if indicator performance requires corrective action. If it does, the corrective action needs to be identified, as well as the employee responsible for its implementation. Then, a timetable for the implementation is assigned, at the end of which the effectiveness of the corrective action is monitored and evaluated. At this point, another indicator can be selected, or a higher threshold can be set, and the process continues.

A well-managed technology planning and management program provides a systematic approach to controlling technology-related risks in all of its phases, from needs analysis to equipment disposition. Equipment-related data elements provide qualitative criteria for equipment performance assessment and obtaining users' perspective in relation to equipment use. Through the development of a failure analysis process, continuous improvement in equipment performance while reducing risk potential in the clinical environment is achievable.

6.3 Codes and Standards

Technology managers faced with limited resources often must choose between alternatives when making decisions. Risk analysis, continuous quality improvement, cost/benefit assessment, and compliance with regulatory mandates are concepts that are vital for the manager who is responsible for managing medical technology. Technology introduces, extends, modifies, or eliminates real as well as perceived risks. Its management requires a mixture of subjective judgment and objective measurement that at times may get lost in the alphabet of the regulatory jargon. For example, the following are key regulatory terms: The Tax Equity and Fiscal Responsibility Act (TEFRA), Diagnosis Related Group (DRG), Prospective Payment System (PPS), Safe Medical Devices Act (SMDA), International Electric Code (IEC), American National Standards Institute (ANSI), Joint Commission on Accreditation of Healthcare Organizations (JCAHO), National Fire Protection Association (NFPA), Medical Information Bus (MIB), National Institute for Occupational Safety and Health (NIOSH), Healthcare Financing Administration (HCFA), Utilization Review (UR), International Classification of Diseases (ICD), Health Maintenance Organization (HMO), and Title 18 Medicare. This is just a small sample of the many mandates and activities that shape the administration of healthcare services.[35]

In response to soaring federal healthcare costs, TEFRA was enacted in 1982. This initiated the PPS that is based on the DRG approach. In October 1983, the federal government began paying hospitals that serve Medicare patients using the DRG approach.[36] The primary emphasis of this Medicare program was cost containment, rather than quality. Quality improvement was mainly due to the JCAHO effort.

Improvement in patient care, clinical performance, and desired outcome are critical elements of a system where codes and regulations are continuously evolving—a system that is shared by many different parties. Equipment manufacturers, engineers, users, regulators, insurance representatives, and public interest groups are establishing and implementing recommended practice guidelines and standards. However, the subject of codes and standards does not generally evoke enthusiasm. Standards may have a greater or lesser impact, but they affect us all. The use of standards affects our lives in various forms and categories, from consumer aspects to workplace activities. Nonetheless, standards must be addressed in their own right in terms of legal, economic, social, and technical considerations.

It is important for the technology manager to understand fully how standards are developed, how they are used and modified, and most significantly, the effect of these activities on the entire spectrum of health-related matters. Standards exist that address protection of the power distribution system in the healthcare facility, protection of individuals from radiation sources (such as lasers and x-rays) and protection of the environment from hazardous substances. The practicing professional should fully appreciate the intent of standards in general and participate in their development and use.

6.4 *Summary*

The hospital is a complex environment integrating different patients, various healthcare professionals, facility, and technology. It is an environment in which safe and effective man-machine interfaces require careful control of human operation, machine performance, and other critical elements. In order to promote a safe, high quality operation, the commitment to risk aversion and to the implementation of the most suitable risk management needs to be accompanied with a commitment to understand pertinent regulations and standards. A clinical engineering program should incorporate methods of risk control and quality improvement into the program's priorities in order to improve the quality and the efficacy of patient care. To do this:

- Involve all your staff.
- Identify medical equipment performance indicators that represent high volume or high risk activities.
- Collect data pertaining to these performance indicators and establish acceptable thresholds for further evaluation.
- Recognize noncompliance, apply corrective measures, and monitor their impact. Report your findings to the hospital's safety committee.
- Implement continuous improvement by selecting other indicators for evaluation or by raising the threshold on existing ones.
- Survey the codes and standards that impact your facility. Consider participation in standards development in an area of particular interest.

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10.0 GLOSSARY

Access - An individual's ability to obtain medical services on a timely and financially acceptable basis.

Appropriate technology - see page 4.

Capital asset - In this book, a capital asset is a durable item that provides service over an extended period of time. Usually a cost-based, or other arbitrary factor, divides assets into "major" or "minor" equipment.

Clinical engineer - A professional who supports and advances patient care by applying engineering and managerial skills to healthcare technology.

Cost-effectiveness - The extent to which a medical technology achieves specified objectives at the lowest possible cost.

Ease of use - see page 6.

Effectiveness - Benefit for a given medical problem under average conditions of use.

Efficacy - Benefit for a given medical problem under ideal conditions of use.

Empowerment - Giving the people who perform the task the authority/responsibility to make change.

Engineering - A profession in which a knowledge of mathematics and natural sciences gained by study, experience, and practice is applied with materials and forces of nature for the benefit of mankind.

Equipment acquisition and deployment - see page 7.

Equipment assets management - see page 7.

Equipment-related risks - Risks associated with the use of medical equipment can be due to one or more of the following causes: equipment function, equipment malfunction, user's error, utility error.

Healthcare technology - see page 2.

Healthcare technology assessment - "An investigative process that examines the consequences of the application and deployment of technology to the delivery of healthcare." Hutton H. Editorial. *Med Prog Tech* 1991; 17:65.

Medical technology management - An interdisciplinary program that utilizes acceptable methods and information to provide guidelines and qualifications for the planning, selection, procurement, maintenance, and replacement of medical hardware, software, and supplies. These guidelines are used to prioritize resource allocations and to maximize the quality and value of care provided.

Quality improvement - A philosophy and methodology, based on W. Edward Deming and Joseph Duran, of proactive approaches that focus on continual assessment and improvement of clinical, hospitality, operational, and administrative processes.

Quality of care - Refers to an organization's objective of care with the most efficient use of resources.

Risk - The probability or likelihood that an adverse effect will occur.

Risk-control program - "An organized and systematic activity aimed at controlling and diminishing the probability of a harmful incident which otherwise may lead to the deterioration of care outcome, decline of staff performance, and worsening of the hospital environment." Cooper JB, Newbower PS, Long CP. Learning from anesthesia mishaps. *QRB/ Quality Review Bulletin.* 1981; 3:10-16.

Risk management - An organized program that removes and controls elements that can contribute to the avoidance of exposure to risks and the minimization of liability exposure.

Safety - A condition of being safe from danger, injury, or damage.

SMDA - Safe Medical Devices Act. This 1990 law sets reporting requirements on "device user facility" such as hospitals, ambulatory surgical facilities, nursing homes, outpatient treatment facilities, and diagnostic facilities following occurrence of medical device-related injury, illness, or death.

Standards - see page 8.

Strategic planning - "A continuous process of making present risk-taking decisions systematically and with greatest knowledge of their futurity; organizing systematically the efforts needed to carry out these decisions; and measuring the results of these decisions against the expectations through organized systematic feedback." Drucker PF. *Management: Tasks, Responsibilities, Practices.* New York, NY: Harper & Row; 1974.

Technology - "The body of tools emerging from the interplay of scientific knowledge and practical operation applied to specialized purposes." Drucker PF. *Management: Tasks, Responsibilities, Practices.* New York, NY: Harper & Row; 1974.

Technology assessment - see page 3.

Technology diffusion - see page 4.

Technology life-cycle - see page 5.

Technology management - A function that coordinates activities within the organization with an objective to achieve results that benefit the organization in both its internal functioning and external relationships.

Technology manager - A professional who is qualified through training and experience to manage medical technology-related programs, programs that systematically support the assessment, planning, acquisition, deployment, maintenance, risk reduction, and replacement of medical equipment and facilities.

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